

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW MEXICO**

MARK GILBERT RIMBERT, individually,
and as Personal Representative of the Estates
of GILBERT JOHN RIMBERT, and
OLIVIA ACOSTA RIMBERT, deceased,

Plaintiff,

vs.

No. CIV 06-0874 JB/LFG

ELI LILLY AND COMPANY,

Defendant.

MEMORANDUM OPINION AND ORDER

THIS MATTER comes before the Court on Defendant Eli Lilly and Company's Motion for Summary Judgment on All Claims, filed March 19, 2008 (Doc. 55) ("Motion"). The Court held a hearing on May 16, 2008. The primary issues are: (i) whether the Court should certify to the Supreme Court of New Mexico the legal issue whether New Mexico law recognizes the learned-intermediary doctrine; (ii) whether the Supreme Court of New Mexico would adopt the learned-intermediary doctrine in prescription-drug cases; (iii) whether the 2003 Prozac warnings were inadequate as a matter of law; (iv) whether Defendant Eli Lilly and Company is entitled to summary judgment on Plaintiff Mark Rimbert's claim for strict liability; (v) whether Eli Lilly is entitled to summary judgment on Mark Rimbert's claim for negligence per se; (vi) whether Eli Lilly is entitled to summary judgment on Mark Rimbert's warranty claims; (vii) whether Eli Lilly is entitled to summary judgment on Mark Rimbert's claim for punitive damages. Because the Court does not believe that the Supreme Court of New Mexico would adopt the learned-intermediary doctrine, and because the Court cannot say that the warnings were adequate as a matter of law, the Court will

grant in part and deny in part Eli Lilly's motion for summary judgment. The Court will grant Eli Lilly summary judgment on Mark Rimbart's warranty and negligence per se claims, and deny it summary judgment on Mark Rimbart's remaining claims.

FACTUAL BACKGROUND

Prozac, an FDA-approved prescription antidepressant that Eli Lilly manufactures, is a selective serotonin reuptake inhibitor ("SSRI"). At the time it was prescribed for Gilbert Rimbart, Prozac was a prescription antidepressant medication that the United States Food and Drug Administration ("FDA") had approved for use in the treatment of major depressive disorder. See Defendant Eli Lilly and Company's Memorandum in Support of its Motion for Summary Judgment on all Claims ¶ 2, at 5, filed March 19, 2008 (Doc. 56) ("Memo. in Support"); Exhibit A to Memo. in Support, Declaration of John M. Plewes, II, M.D. at 3 (taken March 11, 2008) ("Plewes Aff."); Exhibit A to Memo. in Support, Package Insert for Prozac ("Prozac Insert"). Fluoxetine is the generic name for Prozac. See Exhibit C to Memo. in Support, Deposition of Barry Hochstadt, M.D. (taken August 15, 2007) at 23:6-10 ("Hochstadt Depo.").

Before 2003, Barry Hochstadt, M.D., Gilbert Rimbart's primary physician, had read literature regarding whether suicidality could be induced by the use of SSRI medications. See id. at 19:11-20:6.¹ Dr. Hochstadt had been aware of the issue of suicidality in connection with SSRI medications for at least fifteen years. See id. at 19:11-20:6; id. at 53:4-9. Before August of 2003, Dr. Hochstadt had also read literature regarding whether violence could be induced by SSRI

¹ Mark Rimbart objects to Eli Lilly's "statements about Dr. Hochstadt's knowledge from other sources about the risks of Prozac-induced suicidality" as "irrelevant." Plaintiff's Response Memorandum in Opposition to Defendant's Motion for Summary Judgment on All Claims at 2, filed April 17, 2008 (Doc. 74) ("Response"). Mark Rimbart asserts that, "[i]n this failure to warn case, the key is whether there was any warning whatsoever from Lilly itself that their [sic] drug could trigger or increase suicidality in any person." Id.

medications. See id. at 65:20-66:22. Dr. Hochstadt had been aware of the issue of violence in connection with SSRI medications, including Prozac, for at least fifteen years. See id. at 19:11-20:6; id. at 65:20-66:5.

Dr. Hochstadt does not warn patients about an alleged risk of violent activity from antidepressant use because he does not believe that there is any data to support the idea that SSRI medications cause increasing episodes of violence. See id. at 66:6-22. In 2003, if Eli Lilly had told him to do so, Dr. Hochstadt would have monitored patients beginning to use Prozac for suicidality. See id. at 105:15-20.

On August 18, 2003, Gilbert Rimbart went to see Dr. Hochstadt with increasing despondence and depression related to his wife's recent request for a divorce. See Hochstadt Depo. at 34:14-35:11. Dr. Hochstadt concluded that Gilbert Rimbart was not severely depressed using a Zung depression scale. See id. at 101:12-102:24. Dr. Hochstadt diagnosed Gilbert Rimbart with depression and prescribed a 20 milligram daily dose of fluoxetine. See id. at 40:2-41:4; id. at 54:16-21. At the time that Dr. Hochstadt prescribed Prozac for Gilbert Rimbart, a ten milligram dose of Prozac was available. See Prozac Insert at 1; Complaint ¶ 14, at 5. At the time Dr. Hochstadt prescribed Prozac for Gilbert Rimbart, Prozac Weekly, a weekly dose, was available. See Prozac Insert at 1; Complaint ¶ 15, at 15.

Dr. Hochstadt made the decision to prescribe Prozac based on his knowledge and training as a physician. See id. at 123:21-25. When Dr. Hochstadt prescribes any medication, he conducts a risk/benefit analysis. See id. at 23:21-24:2. Dr. Hochstadt relied on medical journals, conferences, textbooks, and the "ePocrates" computer program to educate himself on prescription drugs. Id. at 27:12-28:5. Dr. Hochstadt does not recall Eli Lilly sales representatives calling on him regarding Prozac at the time he prescribed it for Gilbert Rimbart. See id. at 70:18-71:7.

Dr. Hochstadt discussed the risks and benefits of SSRI treatment with Gilbert Rimbart. See Exhibit C to Memo. in Support, Medical Clinic Note (dated August 18, 2003) at 2 (stating “I discussed with him the risks and benefits of treatment using an SSRI. I discussed with him either Prozac or fluoxetine.”). Dr. Hochstadt testified that the implementation of black-box warnings regarding suicide has changed since he treated Gilbert Rimbart, and he could not be sure what he told patients in 2003 about this issue. See id. at 47:17-49:15. Dr. Hochstadt recalled, however, telling Gilbert Rimbart to call his office if he experienced suicidality or worsening depression. See Hochstadt Depo. at 59:16-20; id. at 128:15-129:2.

Dr. Hochstadt testified:

Q. But you are confident that you would have told him in September of 2003, “If your depression gets worse or if you feel suicidal, you need to call me”?

A. I am confident I did that as a routine about that time in my practice career.

Hochstadt Depo. at 59:16-20. Dr. Hochstadt also testified:

Q. And just so that I understand, I thought that your testimony earlier was that in 2003, you would have also counseled patients taking an antidepressant about the risk of suicidality?

A. My understanding and recollection would be yes, even then.

Q. And, in fact, I think you have testified that you would have told Mr. Rimbart at both appointments that he came to see you when he was on Prozac -- actually, the initial appointment in August and then the follow-up in September -- that if he did develop suicidality, he should call you immediately?

A. That would be my recollection.

Id. at 128:15-129:2. Dr. Hochstadt further testified:

Q. . . . You cautioned [patients] because of the concern that their depression could lead to suicide, right?

A. Not true. I only would caution, “If you start this medication, there is a

potential increased risk for suicidality.”

Q. Antidepressant-induced?

A. It could be because of medication, it could be because of their illness. I don’t distinguish. I just say, “If you have increasing problems with, you know, depression, suicidal thinking, then call me immediately and stop the medication.” I can’t distinguish why they would feel that way.

Q. And you are saying you were saying that in August and September of ‘03?

A. My recollection is that’s true. That’s four years ago. So the answer is yes.

Id. at 135:21-136:11.

Mark Rimbert contends that Eli Lilly used the mass media to advertise Prozac. See Response ¶ 78, at 7 (citing www.prozac.com). There is no evidence that Gilbert Rimbert saw any advertisement for Prozac. See Memo. in Support, Exhibit D, Deposition of Tracy Rimbert Thiel at 36:3-9 (taken May 22, 2007)(“Thiel Depo.”).

Dr. Hochstadt did not dispense Prozac to Gilbert Rimbert. See id. at 10:25-11:8. Gilbert Rimbert did not ask for Prozac by name. See id. at 123:17-20. There is no evidence that Gilbert Rimbert had any Prozac prescription filled at a pharmacy. See Deposition of Grace E. Jackson, M.D. at 97:24-99:3 (taken December 13, 2007)(“Jackson Depo.”).

Dr. Hochstadt scheduled a follow-up appointment with Gilbert Rimbert, as it was Dr. Hochstadt’s practice to schedule a three-to-four-week follow-up appointment with patients after he prescribed Prozac. See Hochstadt Depo. at 55:7-17. Gilbert Rimbert did not call Dr. Hochstadt’s office between his August 18, 2003 and September 9, 2003 appointments to report worsening depression or suicidality. See id. at 58:20-59:20.

At the time that Dr. Hochstadt prescribed Prozac for Gilbert Rimbert, the Prozac package insert and the Physicians’ Desk Reference (“PDR”) contained the following statement in the

“Precautions” section:

Suicide -- The possibility of a suicide attempt is inherent in depression and may persist until significant remission occurs. Close supervision of high risk patients should accompany initial drug therapy. Prescriptions for Prozac should be written for the smallest quantity of capsules consistent with good patient management, in order to reduce the risk of overdose.

Prozac Insert at 2; Exhibit B to Memo. in Support, PDR at 5 (emphasis in original). Mark Rimbert objects that the reference to suicide in the “Precautions” section of the labeling in 2003 was in regard to suicide as a consequence of depression. Response at 3. The “Adverse Reactions” sections of the Prozac Insert and the PDR, however, also reference suicide attempt, akathisia, and hostility. Prozac Insert at 4; PDR at 7. The “Postintroduction Reports” section of the Prozac Insert and the PDR also listed suicidal ideation and violent behaviors as being included in post-marketing reports of adverse events temporally associated with Prozac. Prozac Insert at 4; PDR at 7.

At the time of his deposition, Dr. Hochstadt was aware that a black-box warning identifying a possible risk of increased suicidality in pediatric patients and young adults treated with SSRIs was added to the Prozac labeling and Prozac Insert sometime in 2004. See Hochstadt Depo. at 16:9-15, id. at 20:11-15. The federal regulations required and require a warning in the “Warnings” section about the risk of Prozac-induced suicidality. Response, Exhibit 3, 2003 Prozac label at 9; 21 C.F.R. §§ 201.57(e)(June 30, 2006) and 314.70(c)(2)(i). Mark Rimbert asserts that the “passing references to akathisia or suicidality or hostility or violence in other sections of the labeling that are not ‘warnings’ are irrelevant.” Response at 3.

Mark Rimbert contends that the risk of akathisia, mania, psychosis, violence, activation, and/or suicide is dose dependent. See Response ¶ 44, at 3-4; Exhibit 4, R. Perlis et. al, Treatment-Associated Suicidal Ideation and Adverse Effects in an Open, Multicenter Trial of Fluoxetine for Major Depressive Episodes, 76 Psychotherapy and Psychosomatics 40-46 (2007)(“Beasley article”);

Defendant Eli Lilly and Company's Answer to Plaintiff's Complaint ¶ 13 at 5, filed November 20, 2006 ("Lilly admits that some, but not all, adverse events associated with the use of Prozac appear to be dose related."). Mark Rimbert asserts that, "[i]n other words, if one is already sensitive to Prozac-induced side effects, for whatever reason, increased dosing exacerbates the issue." Response at ¶ 44, at 4. Mark Rimbert contends that the FDA agrees. See Response ¶ 44, at 4; Prozac Insert at 10 (stating that "[a]ll patients being treated with antidepressants for any indication should be monitored appropriately and observed closely for clinical worsening, suicidality, and unusual changes in behavior, especially during the initial few months of a course of drug therapy, or at times of dose changes, either increases or decreases.").

There is a 2008 black-box warning that contains the words of caution for patients of "all ages." Response, Exhibit 2, Prozac Insert at 1, available at: www.prozac.com ("2008 Prozac Insert"). As of August of 2003, however, when Dr. Hochstadt prescribed Prozac for Gilbert Rimbert, there was no black-box warning. See Complaint ¶¶ 2, 32-36, 48(c), 51, 55, at 1, 11-12, 15, 16; Plewes Aff. at 1-2, Prozac Insert at 6. Mark Rimbert contends that, in 2003, none of the inserts warned about Prozac-related "iatrogenic violence." Response at 2-3.

Dr. Hochstadt has read, and is familiar with, the 2007 Prozac Insert which includes the black-box warning. See Hochstadt Depo. at 17:11-18:4. Dr. Hochstadt is confident that, even with the knowledge that a black-box warning has been added to SSRI medication, he would have prescribed Prozac for Gilbert Rimbert in 2003. See id. at 67:19-23. Dr. Hochstadt testified that, now that the black-box warnings regarding suicide have been implemented, he warns patients about the risk of antidepressant-associated suicidality. See id. at 49:15-25.

On September 8, 2003, Gilbert went to Dr. Tamara Goodman at the Veterans' Administration ("VA") for refills of medications. See Exhibit F to Memo. in Support, Progress Note

at 2 (dated September 8, 2003). Dr. Goodman's Progress Note does not address Gilbert Rimbart's depression or use of Prozac. See id. The Progress Note does not identify any side effects associated with Gilbert Rimbart's use of Prozac. See id.

Gilbert Rimbart went to Dr. Hochstadt for follow up on September 9, 2003. See Hochstadt Depo. at 56:10-18. Gilbert Rimbart told Dr. Hochstadt that his use of Prozac "t[ook] the edge off," but that he had not experienced a dramatic improvement in his depression. Id. at 57:3-10. Gilbert Rimbart reported no side effects from Prozac to Dr. Hochstadt on September 9, 2003 nor at any other time. See id. at 56:19-57:4.

On September 9, 2003, Dr. Hochstadt increased Gilbert Rimbart's daily dose of Prozac from 20 milligrams to 40 milligrams. See id. at 64:4-9. Mark Rimbart contends that doubling the dose on September 9, 2003 increased Gilbert Rimbart's risk of "potentially lethal side effects." Response at ¶ 44, at 4. Mark Rimbart contends that "[t]he Rimbarts' deaths on September 25, 2003, was, thus, in the very time period that one would, according to peer-reviewed articles published by Lilly authors and the FDA, expect for a Prozac-induced event." Response at ¶ 44, at 4.

At the September 9, 2003 follow-up appointment, Dr. Hochstadt again advised Gilbert to contact the office immediately if he experienced suicidality or worsening depression. See id. at 62:9-22. Dr. Hochstadt testified:

- Q. It appears in this note that Mr. Rimbart's next visit after this September 9th, 2003, visit was scheduled for November; is that accurate?
- A. That is my understanding, looking at the medical record, that I stated, "Prior to the next visit in November."
- Q. But then it goes on to say, "The patient will return sooner if he is having difficulty or problems"?
- A. That is correct.

Q. Is there an indication that you would have told him, “If you start having any type of further problems or difficulties, you need to come back and see me”?

A. That’s correct.

Id. at 62:9-22. In 2003, and currently, it is Dr. Hochstadt’s practice to follow up with a patient one to two months after an increase in dose. See id. at 55:18-56:1. Dr. Hochstadt had no further contact with Gilbert Rimbart after September 9, 2003. See id. at 56:12-15. Dr. Hochstadt still considers his decision to treat Gilbert Rimbart with Prozac appropriate, both in initially prescribing Prozac and increasing the dose of Prozac. See id. at 67:11-18.

On September 25, 2003, Gilbert and Olivia Rimbart were found dead in their home. See Complaint ¶ 44, at 14; Exhibit H to Memo. in Support, Supplementary Offense Report (dated October 24, 2003)(“Police Report”); Deposition of Mark Rimbart (taken May 23, 2007) at 157:1-158:23 (“M. Rimbart Depo.”). Olivia Rimbart and the family dog were covered with blankets. See M. Rimbart Depo. at 158:8-10; id. at 161:4-8; Police Report at 4. Gilbert Rimbart was seated at the kitchen table. See M. Rimbart Depo. at 157:7-165:22. On the table in front of Gilbert Rimbart were a note, a list of assets, bank account numbers, and the wills of Gilbert and Olivia Rimbart. See id. at 163:10-165:14. The note, in Gilbert Rimbart’s handwriting, stated, in its entirety:

I know you kids will never be able to forgive me! I love your mother more then life!
Will be together now for eternity

Love Dad

M. Rimbart Depo., Ex. 3.

Investigators concluded that Gilbert Rimbart shot Olivia Rimbart multiple times, causing her death. See Police Report at 9; Exhibit I to Memo. in Support, Death Certificate for Olivia A. Rimbart (dated September 25, 2003)(stating that the cause of death were gunshot wounds of trunk and extremities). The medical examiner concluded that Gilbert Rimbart died from a self-inflicted

gunshot wound to the head. See Exhibit I to Memo. in Support, Death Certificate for Gilbert John Rimbart (dated September 25, 2003)(stating that the cause of death was gunshot wound of head).

A bottle marked Prozac was on the table where Gilbert Rimbart was seated. See M. Rimbart Depo. at 28:23-29:5. The bottle did not have a pharmacy label, nor did it state Gilbert Rimbart's name or other identifying information. See Exhibit J to Memo. in Support, Deposition of Yvonne Rimbart at 14:23-16:14 (taken May 23, 2007)("Y. Rimbart Depo."). Family members found an unfilled prescription for Prozac written for Gilbert Rimbart when they cleaned the home after his death. See id. at 15:15-17:4. The presence of fluoxetine and its psychoactive metabolite, norfluoxetine, in Gilbert Rimbart's blood was confirmed by toxicological examination. See Exhibit 5 to Response, National Medical Services, Inc. Toxicology Report (dated February 26, 2004) at 1 ("Toxicology Report"). The homicide/suicide in this case occurred sixteen days after Gilbert's dose of Prozac was doubled. See Memo. in Support at ¶¶ 32, 39, at 10-11. Mark Rimbart alleges that his father, Gilbert Rimbart, shot and killed Olivia Rimbart, his mother, as a result of ingesting Prozac. See Complaint ¶¶ 44-46, at 14-15, filed September 18, 2006 (Doc. 1)("Complaint").

In the fall of 2004, the FDA decided that, in addition to the black-box warning on the label or the package insert for physicians, that patients needed to be warned directly, via "Patient Medication Guides" about the risks at issue in this lawsuit. Response at 5; Exhibit 6 to Response, FDA Public Health Advisory at 1 (dated October 15, 2004), available at: <http://www.fda.gov/cder/drug/antidepressants/SSRIPHA200410.htm>; Exhibit 7, 2008 Patient Medication Guide ("Patient Medication Guide").

In May of 2006, David N. Juurlink, M.D., and others, published an article entitled The Risk of Suicide with Selective Serotonin Reuptake Inhibitors in the Elderly. See Exhibit 9 to Response, D. Juurlink et al., The Risk of Suicide with Selective Serotonin Reuptake Inhibitors in the Elderly,

163:5 Am. J. Psychiatry 813-21 (2006)(“Juurlink article”). The FDA cited to this article in a Memorandum it issued in 2006. See Exhibit 10 to Response, Memorandum from Thomas P. Laughren, M.D., Director, Division of Psychiatry Products, to Members of the Psychopharmacologic Drugs Advisory Committee at 8 (dated November 16, 2006)(citing Juurlink article). The authors of the Juurlink article found a five-fold increase of violence in the first four weeks of treatment, and explained that this increase was not incongruent with a protective effect for patients who have a therapeutic response to the drug over a long period of time. See Juurlink article at 1.

In December of 2006, Dr. Charles Beasley, a physician that Eli Lilly employed, published a peer-reviewed article that he co-authored with Roy H. Perlis. See Beasley article; Exhibit 8 to Response, Deposition of Charles Beasley, M.D. at 13:2-16:45(taken June 27, 2007)(“Beasley Depo.”) in Ebel v. Eli Lilly and Co., No. 1:04-cv-00194 (S.D. Tex. 2007). In-house Eli Lilly physicians and scientists reviewed the Beasley article, and Eli Lilly ultimately approved it for publication. See Beasley Depo. at 13:2-18:13. Dr. Beasley’s article discusses a “small subset” of patients who exhibit the emergence or worsening of suicidal ideas or behavior upon initiation of Prozac therapy. Beasley article at 45 (stating that “[e]ven interventions which help the majority of patients may be associated with worsening in a small subset.”). The article states:

Consistent with a previous analysis of suicidal behavior, the majority of new [suicidal ideation] emerged within the first 4 weeks, with the greatest incident in the first week. This result suggests that the initial 4-week treatment period is one where vigilance is particularly important. On the other hand, some additional [suicidal ideation] emerged later in the study, indicating that individuals remain vulnerable to the emergence of [suicidal ideation] after the initial month.

Id. at 44. The Beasley article also states “[i]t is thus impossible to establish a specific association between fluoxetine and treatment-emergent adverse events or between fluoxetine and treatment-

emergent [suicidal ideation] -- the observed events could also represent nonspecific (placebo-like) effects or simply natural fluctuation in depression itself.” Id. at 45.

PROCEDURAL BACKGROUND

Mark Rimbart has disclosed one retained expert, Grace E. Jackson, M.D. See Memo. in Support, Plaintiff’s Expert Disclosure at 1, filed March 19, 2008 (Doc. 56-12)(“Plaintiff’s Expert Disclosure”). Mark Rimbart disclosed Dr. Jackson as an expert on “general and specific causation as well as Eli Lilly’s failure to warn and/or appropriately test fluoxetine.” Id. at 1. In her report, Dr. Jackson opined:

Had Lilly provided an adequate warning about the risks of Prozac to Gilbert Rimbart, his family and his physicians; had Lilly provided an adequate warning about the necessity of vigilant monitoring (particularly when changing dose, or initiating and terminating drug therapy); and had Lilly promptly communicated the facts about the likelihood of treatment-emergent suicidality and the early worsening of depression, it is quite possible that the violent deaths of Gilbert Rimbart, his wife, and his dog could have been avoided.

Exhibit G to Defendant Eli Lilly and Company’s Memorandum in Support of its Motion to Exclude Expert Testimony of Dr. Grace Jackson, filed March 20, 2008 (Doc. 59), Report of Grace E. Jackson, M.D. at 52 (dated November 1, 2007), filed March 20, 2008 (Docs. 63-9 and 63-10)(“Jackson Report”). Eli Lilly points out that Dr. Jackson’s report does not include any opinion or claim that Prozac was defectively designed. See Memo. in Support ¶ 55, at 13. Eli Lilly also notes that Dr. Jackson’s report does not include any opinion or claim that the Prozac Gilbert Rimbart allegedly ingested was defectively manufactured. See id. ¶ 56, at 13.

Dr. Jackson testified that she is not an expert on prescription-drug warnings. See Jackson Depo. at 204:15-23. Dr. Jackson testified that she is not an expert on prescription-drug marketing. See id. at 210:22-24. Dr. Jackson testified that she is not an expert on FDA regulations relating to product labeling, nor has she read the FDA regulations that govern labeling. See id. at 203:17-20,

id. at 204:11-14.

Dr. Jackson did not propose an alternative warning for Prozac. See id. at 204:15-23. Dr. Jackson testified that she did not “feel qualified,” based on her training or experience, to draft a warning for Prozac. Id. at 204:20-23. Mark Rimbart contends that “Dr. Jackson does not have to be a regulatory expert or an expert in drafting warnings to know what kind of information Lilly should have included in a warning or how the lack of such a warning contributed to Plaintiff’s injuries.” Response at 5. Mark Rimbart contends that Dr. Jackson’s “credentials as a practicing psychiatrist and psychoactive medication researcher, licensed to prescribe medications of this nature, are sufficient.” Id.

Dr. Jackson acknowledged that completed suicide is a risk factor of major depressive disorder independent of Prozac. See Jackson Depo. at 100-22-101:9. She testified:

Q. And you, of course, would agree that suicidality -- in fact, completed suicide -- is a risk of major depressive disorder?

A. Correct.

Q. In fact, it’s one of the diagnosis criteria of major depressive disorder, suicidality, isn’t it?

A. It is one of the possible symptoms of major depressive disorder.

Q. And -- and it’s -- and it’s a -- and it’s a possible symptom and a possible outcome of major depressive disorder, totally independent of taking Prozac, right?

A. Correct.

Id. at 100:22-101:9. Dr. Jackson could not eliminate alternative causes of the deaths of Gilbert and Olivia Rimbart. See id. at 148:22-149:3; id. at 149:12-22. Mark Rimbart contends that, “[b]ecause suicide is multi factorial, it is not necessary for an expert to ‘eliminate’ alternative contributing factors that ‘possibly’ contributed to a person’s death. The question is whether or not one of the

proximate causes is, more likely than not, the Prozac.” Response at 5.

Dr. Jackson also testified that, to bring about the death of his dog, his wife, and ultimately himself, Gilbert Rimbart had to engage in eleven deliberative acts. See Jackson Depo. at 129:17-135:1. Dr. Jackson acknowledged that there was no evidence on the record that Gilbert Rimbart received any communication from Eli Lilly before being proscribed Prozac. See id. at 110:10-111:7. Dr. Jackson also acknowledged that there was no evidence that Gilbert Rimbart requested Dr. Hochstadt proscribe Prozac for him. See id. at 110:22-111:1. Dr. Jackson testified that she did not know if a single isomer version of Prozac would qualify as a safe and effective treatment for major depressive disorder. See id. at 296:15-297:2; Complaint ¶¶ 18-22, at 6-7.

Eli Lilly moved for summary judgment on March 19, 2008. See Motion at 1. Eli Lilly contends that each of Mark Rimbart’s claims -- negligence, negligence per se, strict liability, and breach of warranty -- fails for want of proof and as a matter of law, and that summary judgment in Eli Lilly’s favor is appropriate. See Complaint ¶¶ 2, 44 at 1, 14. Eli Lilly contends that the Court should dismiss each of Mark Rimbart’s claims with prejudice. See id.

At the June 27, 2008 hearing, Eli Lilly argued that the learned-intermediary cases have withstood the test of time, see Transcript of Hearing at 26:21-23 (See), filed June 27, 2008 (Doc. 103)(“Tr.”),² and that the learned-intermediary doctrine is the law in New Mexico. See id. at 12:17-20 (See). Eli Lilly contended that three New Mexico cases have adopted the learned-intermediary doctrine: Serna v. Roche Labs, 101 N.M. 522, 524, 684 P.2d 1187, 1189 (Ct. App. 1984), Perfetti v. McGhan Med., 99 N.M. 645, 662 P.2d 646, 651 (Ct. App. 1983), and Hines v. St. Joseph’s Hosp., 86 N.M. 763, 764, 527 P.2d 1075, 1076 (Ct. App. 1974). See Tr. at 6:9-22 (Court & See). Eli Lilly

² The Court’s citations to the transcript of the hearing refer to the Court Reporter’s original, unedited version. Any final transcript may contain slightly different page and/or line numbers.

stated that State ex rel. Johnson and Johnson Corp. v. Karl, 647 S.E.2d 899 (W.Va. 2007), was the only case of which it was aware that completely rejected the learned-intermediary doctrine. See Tr. at 7:12-18 (Court & See). Eli Lilly opposed certification to the Supreme Court of New Mexico the question whether the Supreme Court of New Mexico would adopt the learned-intermediary doctrine. Eli Lilly argued that, for a question to be certified to the Supreme Court of New Mexico, it must be a novel or unsettled issue, and that the learned-intermediary doctrine is not a novel or unsettled issue under New Mexico law. See id. at 70:18-271:1-6 (See & Court).

Eli Lilly also contended that the warnings of suicidal ideation, attempted suicide, violent behaviors, akathisia, delusions, psychosis, and agitation were all contained in the 2003 Prozac insert and thus the insert should be considered adequate as a matter of law. See id. at 11:19-24 (See). Eli Lilly asserted that Mark Rimbart has made no showing that “a different warning would affect the outcome in the case.” Id. at 19:21-23 (See). Eli Lilly argued that Mark Rimbart’s case fails for failure to show proximate cause because there is no showing that Dr. Hochstadt would have done anything differently. See id. at 20:24-21:1-7 (See).

Eli Lilly maintained that there is no evidence that Gilbert Rimbart was affected by direct-to-consumer advertising or internet advertising. See id. at 23:14-21 (See). Eli Lilly further asserts that Mark Rimbart’s claim fails because the FDA states that there is no increased risk of suicide for people over the age of sixty-five, Gilbert Rimbart’s age, and yet Mark Rimbart’s position is that Eli Lilly violated 21 C.F.R. § 201.57(e) by not stating that Prozac can cause suicidality. See id. at 31:5-6 (See); id. at 32:21-25 (See).

Mark Rimbart asserted that judges have created the learned-intermediary doctrine as a matter of common law, and that it has no support in the Restatement (Second) of Torts. See id. at 39:7-12 (Vickery). Mark Rimbart contended that the first codification of the learned-intermediary doctrine

was in 1998 in the Restatement (Third) and that the New Mexico cases upon which Eli Lilly relies do not use the term learned-intermediary doctrine. See id. at 39:16-23 (Vickery). Mark Rimbart conceded that no other courts have done what the West Virginia court did in State ex rel. Johnson and Johnson Corp. v. Karl. See Tr. at 47:5-8 (Court & Vickery).

Mark Rimbart contended, however, that the Supreme Court of New Mexico would reject the learned-intermediary doctrine because it adopted the strict liability doctrine in 1972 for the following policy reasons: to compensate victims of dangerous products, and to put the legal responsibility on those who can most afford it and do something about dangerous products. See id. at 51:4-16 (Vickery). Mark Rimbart argued that he believed the Supreme Court of New Mexico would adopt the read-and-heed presumption. See id. at 63:6-10 (Vickery). Mark Rimbart argued that, if the Court were to certify a question to the Supreme Court of New Mexico, “then we will have a definitive authoritative answer on a pure question of law.” Id. at 37:20-21 (Vickery).

Mark Rimbart noted that, if Gilbert Rimbart were alive today, he would receive a package insert with a black-box warning about aggression and hostility, stating that patients of all ages need to be monitored, and he would receive a medication guide written in plain English focused on the risks of violence and suicide. See id. at 35:15-36:3 (Vickery).

On June 3, 2008, Eli Lilly filed a motion seeking leave to file a post-hearing memorandum in support of its motion for summary judgment on all claims. See Defendant Eli Lilly and Company’s Motion for Leave to File Post-Hearing Memorandum in Support of Its Motion for Summary Judgment on All Claims at 1, filed June 3, 2008 (Doc. 100)(“Motion for Leave to File Post-Hearing Memo.”). Attached to Eli Lilly’s motion was its post-hearing memorandum. See Exhibit 1 to Motion for Leave to File Post-Hearing Memo., Defendant Eli Lilly and Company’s Post-Hearing Memorandum in Support of its Motion for Summary Judgment on All Claims, filed

June 3, 2008 (Doc. 100-2)(“Post-Hearing Memo.”).

In its post-hearing memorandum, Eli Lilly repeats some of the arguments it makes in its motion for summary judgment. See Post-Hearing Memo. at 1-10. Eli Lilly contends that, were the Court to predict that the Supreme Court of New Mexico would not apply the learned-intermediary doctrine, such a ruling “should be applied only prospectively.” Id. at 11. Eli Lilly argues that the factors in Beavers v. Johnson Controls World Services, Inc., 118 N.M. 391, 881 P.2d 1376 (N.M. 1994), would favor a prospective-only application of “any prediction that New Mexico courts would no longer recognize and apply the learned intermediary doctrine.” Post-Hearing Memo. at 11. Eli Lilly also contends that, even if it had a duty to directly warn patients, Mark Rimbart has not come forward with evidence that it owed any duty to provide the warning that he advocates or that such a warning would have prevented the deaths of Gilbert and Olivia Rimbart. See id. at 13. Eli Lilly again opposes certification to the Supreme Court of New Mexico, even after the Court gave a tentative ruling on the issue of the learned-intermediary doctrine. See id. at 1-2 (“Under such circumstances, certification of a question concerning New Mexico’s recognition of the learned intermediary doctrine would not be justified or appropriate under NMRA, Rule 12-607(A)(1).”).

On August 18, 2008, Mark Rimbart's counsel, Mr. Andy Vickery, wrote a letter to the Court, in response to the Court's Memorandum Opinion and Order granting Defendant Eli Lilly and Company's Motion for Leave to File Post-Hearing Memorandum in Support of its Motion for Summary Judgment on All Claims, filed August 18, 2008 (Doc. 108). See Letter from Andy Vickery to the Court (dated August 18, 2008)(“August 18, 2008 Letter”). Mr. Vickery indicated that he saw “no reason to further burden the Court with additional briefing.” Id. He noted that the only issue raised by Eli Lilly that he had not addressed was the retroactive/prospective application issue. He stated: “However, even if the Court chose to ignore the New Mexico presumption that its

decision should apply retroactively, it would still presumably apply its decision in favor of the litigants in this case." Id. Mr. Vickery indicated that, unless the Court believed that further briefing or argument from Mark Rimbart or his counsel would be helpful, they would not seek further supplementation and that "accordingly, . . . the Motion is ripe for ruling." Id.

LAW REGARDING SUMMARY JUDGMENT

Summary judgment is proper and appropriate where the movant demonstrates that "there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law." Fed. R. Civ. P. 56(c). See Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 250 (1986); Quaker State Minit-Lube, Inc. v. Fireman's Fund Ins. Co., 52 F.3d 1522, 1527 (10th Cir.1995)("Summary judgment is proper only if the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law.")(internal quotations omitted); Thrasher v. B and B Chem. Co., 2 F.3d 995, 996 (10th Cir.1993). Summary judgment is "properly regarded not as a disfavored procedural shortcut, but rather as an integral part of the Federal Rules as a whole, which are designed 'to secure the just, speedy and inexpensive determination of every action.'" Celotex Corp. v. Catrett, 477 U.S. 317, 327 (1986)(quoting Fed. R. Civ. P. 1). The movant bears the initial burden of showing that there is an absence of evidence to support the nonmoving party's case. See La Casa de Buena Salud v. United States, No. CIV 07-238 JB/RHS, 2008 WL 2323495 at *14 (D.N.M. March 21, 2008)(Browning, J.)(citing Bacchus Indus., Inc. v. Arvin Indus., Inc., 939 F.2d 887, 891 (10th Cir.1991)). Once the movant meets this burden, rule 56(e) requires the nonmoving party to designate specific facts showing that there is a genuine issue for trial. See Celotex Corp. v. Catrett, 477 U.S. at 324.

While the party moving for summary judgment has the initial burden of establishing that

there is an absence of evidence to support the opposing party's case and the moving party is entitled to judgment as a matter of law, see id. at 330, once the moving party meets its burden, the party opposing the motion must come forward with specific facts supported by admissible evidence that demonstrates the presence of a genuine issue for trial, see Anderson v. Liberty Lobby, Inc., 477 U.S. at 248-249; Biester v. Midwest Health Servs., Inc., 77 F.3d 1264, 1266 (10th Cir.1996). When the record, taken as a whole, could not lead a rational trier of fact to find for the non-moving party, there is no genuine issue for trial. See Matsushita Elec. Indus. Co. v. Zenith Radio Corp., 475 U.S. 574, 587 (1986). “[W]here the moving party has the burden -- the plaintiff on a claim for relief or the defendant on an affirmative defense -- his showing must be sufficient for the court to hold that no reasonable trier of fact could find other than for the moving party.” Paul v. Monts, 906 F.2d 1468, 1474 (10th Cir. 1990)(internal quotations omitted).

The Tenth Circuit has explained:

In cases arising under diversity jurisdiction, the federal court's task is not to reach its own judgment regarding the substance of the common law, but simply to ascertain and apply the state law. . . . The federal court must follow the most recent decisions of the state's highest court. . . . Where no controlling state decision exists, the federal court must attempt to predict what the state's highest court would do. . . . In doing so, it may seek guidance from decisions rendered by lower courts in the relevant state, . . . appellate decisions in other states with similar legal principles, . . . district court decisions interpreting the law of the state in question, . . . and the general weight and trend of authority in the relevant area of law. . . . Ultimately, however, the Court's task is to predict what the state supreme court would do.

Wade v. Emcasco Ins. Co., 483 F.3d 657, 665-66 (10th Cir. 2007)(citations and internal quotation marks omitted and emphasis added).

LAW REGARDING CERTIFICATION TO THE SUPREME COURT OF NEW MEXICO

N.M.R.A. Rule 12-607 provides:

A. Power to answer.

(1) The Supreme Court may answer by formal written opinion questions of law certified to it by a court of the United States, an appellate court of another state, a tribe, Canada, a Canadian province or territory, Mexico or a Mexican state if the answer may be determinative of an issue in pending litigation in the certifying court and the question is one for which answer is not provided by a controlling:

(a) appellate opinion of the New Mexico Supreme Court or the New Mexico Court of Appeals; or

(b) constitutional provision or statute of this state.

N.M.R.A. 12-607(A)(1). See, e.g., Walker v. United States, 2007-NMSC-038, ¶ 1, 162 P.3d 882, 47 (answering questions certified by the United States Court of Federal Claims); Campos v. Murray, 2006-NMSC-020, ¶ 2, 134 P.3d 741, 742 (answering questions certified by United States District Judge Black of the District of New Mexico). Federal courts have the option of determining what a state court would do if confronted with the same issue, see Erie R.R. Co. v. Tompkins, 304 U.S. 64, 78 (1938), or of certifying the question to the state appellate court for review, see Allstate v. Stone, 116 N.M. 464, 465, 863 P.2d 1085, 1086 (1993)(“This matter comes before us by way of certification from the United States District Court for the District of New Mexico.”). See Lehman Bros. v. Schein, 416 U.S. 386, 390-91 (1974)(“The decision to certify a question to the state supreme court ‘rests in the sound discretion of the federal court.’ ”); Farm Bureau Mut. Ins. Co. v. Jameson, 472 F.Supp.2d 1272, 1280 (D.N.M. 2006)(Browning, J.). Pursuant to N.M.S.A. 1978, § 39-7-4, the Supreme Court of New Mexico may answer questions that the federal district court certifies to it if they involve propositions of New Mexico law that may be determinative of the matter before the certifying court and there are no controlling precedents from New Mexico appellate courts. See Swink v. Fingado, 115 N.M. 275, 276, 850 P.2d 978, 979 n.1 (1993); Schlieter v. Carlos, 108 N.M. 507, 508, 775 P.2d 709, 710 (1989).

In Stoner v. New York Life Insurance Co., 311 U.S. 464 (1940), the Supreme Court of the

United States explained that, “in cases where jurisdiction rests on diversity of citizenship, federal courts, under the doctrine of Erie Railroad Co. v. Thompkins . . . must follow the decisions of intermediate state courts in the absence of convincing evidence that the highest court of the state would decide differently.” 311 U.S. at 467. “In particular, this is true where the intermediate state court has determined the precise question in issue in an earlier suit between the same parties, and the highest court of the state has refused review.” Id. See Adams-Arapahoe Joint School Dist. No. 28-J v. Continental Ins. Co., 891 F.2d 772, 774 (10th Cir. 1989)(“With respect to issues which the Colorado Supreme Court has not addressed, we may consider all available resources, including Colorado appellate court decisions, other state and federal decisions, and the general trend of authority, to determine how the Colorado Supreme Court would construe the law in this case.”).

As the Tenth Circuit explained in Wade v. Emcasco Insurance Co., 483 F.3d 657 (10th Cir. 2007):

In cases arising under diversity jurisdiction, the federal court's task is not to reach its own judgment regarding the substance of the common law, but simply to ascertain and apply the state law. . . . The federal court must follow the most recent decisions of the state's highest court. . . . Where no controlling state decision exists, the federal court must attempt to predict what the state's highest court would do. . . . In doing so, it may seek guidance from decisions rendered by lower courts in the relevant state . . . appellate decisions in other states with similar legal principles . . . district court decisions interpreting the law of the state in question, . . . and the general weight and trend of authority in the relevant area of law. . . . Ultimately, however, the Court's task is to predict what the state supreme court would do. Our review of the district court's interpretation of state law is de novo.

483 F.3d at 665-66 (internal citations and quotation marks omitted).

NEW MEXICO LAW REGARDING FAILURE-TO-WARN CLAIMS

Under New Mexico law, to prevail on a negligence claim, a plaintiff must establish: (i) the existence of a duty owed to the plaintiff; (ii) a breach of such duty; (iii) a causal connection between a defendant's conduct and the injury to the plaintiff; and (iv) damages resulting from such conduct. See Parker v. E.I. DuPont deNemours and Co., Inc., 121 N.M. 120, 130, 909 P.2d 1, 11 (Ct. App.

1995). A plaintiff in a product-liability action must prove every essential element of his claim by a preponderance of the evidence. See N.M.R.A., Civ. UJI 13-304. Proving a fact by a preponderance of the evidence means establishing that something is more likely true than not true. See Santa Fe Pub. Sch. v. Romero, 37 P.3d 100, 103 (N.M. Ct. App. 2001). Evenly balanced evidence is not sufficient to meet this burden. See N.M.R.A., Civ. UJI 13-304 (“Evenly balanced evidence is not sufficient.”). Moreover, proximate cause must be shown as a probability, not a possibility. See Alberts v. Schultz, 1999-NMSC-015, ¶ 28, 975 P.2d 1279, 1286 (stating that “causation must be proved to a probability, but not to a certainty”); Alfonso v. Lund, 783 F.2d 958, 964 (10th Cir. 1986)(“Nevertheless, we feel that under New Mexico law, a medical malpractice case is defective if . . . the expert testimony indicated that negligence as the proximate cause of the injury was only a possibility, not a probability.”); Buchanan v. Downing, 74 N.M. 423, 426, 394 P.2d 269, 271 (N.M. 1964)(“Even at best, the expert testimony indicated that negligence as the proximate cause of this injury was only a possibility, not a probability, and therefore there is no testimony, expert or otherwise, to show the proximate cause of the injury.”).

1. Duty to Warn and the Learned-Intermediary Doctrine.

Pursuant to the learned-intermediary doctrine, the prescribing physician acts as a learned intermediary between a prescription drug manufacturer and the ultimate user, and the manufacturer satisfies its duty to warn by providing adequate warnings to the prescribing physician. See, e.g., Reyes v. Wyeth Labs., 498 F.2d 1264, 1276 (5th Cir. 1974)(“Prescription drugs are likely to be complex medicines, esoteric in formula and varied in effect. As a medical expert, the prescribing physician can take into account the propensities of the drug, as well as the susceptibilities of his patient.”); Hill v. Searle Labs, 884 F.2d 1064, 1070 (8th Cir. 1989)(noting that the learned-intermediary doctrine is justified because it is virtually impossible for a manufacturer to directly

warn each patient and that imposing a duty on manufacturers to warn patients directly would interfere with the relationship between the doctor and patient). In Wright v. Abbott Laboratories, Inc., 259 F.3d 1226 (10th Cir. 2001), the Tenth Circuit affirmed dismissal of failure-to-warn claim pursuant to learned-intermediary doctrine under Kansas law. See 259 F.3d at 1233-34. The Tenth Circuit noted:

The learned intermediary doctrine states that once a manufacturer warns a doctor about a drug's inherent dangers, it has fulfilled its legal duty to provide a warning. See Hall v. Merck, Sharp & Dohme, 774 F.Supp. 604, 605-06 (D.Kan.1991) (granting summary judgment to a drug manufacturer because it discharged its legal duty to plaintiff by warning prescribing physician of drug's inherent risks); Phelps v. Sherwood Med. Indus., 836 F.2d 296, 301-03 (7th Cir.1987). Under Kansas law, a plaintiff cannot prevail against a prescription drug manufacturer in a failure to warn case where the manufacturer warned the learned intermediary of the drug's inherent risks.

Wright v. Abbott Labs., Inc., 259 F.3d at 1233 (internal quotation marks omitted).

“The overwhelming majority of jurisdictions to address this issue apply the learned intermediary doctrine to define a pharmaceutical company’s duty to warn of risks associated with the use of a prescription drug.” In re Norplant Contraceptive Prod. Liab. Litig., 215 F.Supp.2d 795, 806 (E.D. Tex. 2002)(citing Serna v. Roche Lab., 101 N.M. 522, 524, 684 P.2d 1187, 1189 (Ct. App. 1984), and Hines v. St. Joseph's Hosp., 86 N.M. 763, 527 P.2d 1075 (Ct.App. 1974)).

In Perfetti v. McGhan Medical, 99 N.M. 645, 662 P.2d 646 (Ct. App. 1983), a surgeon inserted a mammary prosthesis into the plaintiff. See 99 N.M. at 648, 662 P.2d at 647. Approximately twenty-five months after the prosthesis was implanted, it deflated. See id. at 648, 662 P.2d at 647. When the surgeon removed the prosthesis, a split about a half an inch on the front and half an inch on the back was discovered. See id., 662 P.2d at 647. The prosthesis was manufactured by the defendant. See id., 662 P.2d at 647. The Court of Appeals stated that “[a] manufacturer of a product . . . which is obtainable only through the services of a physician, fulfills

its duty if it warns the physician of the dangers attendant upon its use, and need not warn the patient as well.” Id., 662 P.2d at 649 (internal quotation marks omitted). The Court of appeals stated:

In this case the trial court could have ruled that there was no factual issue as to the adequacy or properness of defendant's warning as to the nature and extent of the danger, and that the warning was deficient as a matter of law. Although the surgeon knew generally of the danger of deflation, he had only minimum knowledge of delayed deflation at the time the prosthesis was implanted. The surgeon expected the prosthesis to last from 10-to-15 years and would not have used the prosthesis if he had been aware of the danger resulting from wear due to a fold in the prosthesis. A witness for defendant testified there is a 20-to-30 percent incidence of capsular contracture where there has been a subcutaneous mastectomy, that the manufacturer was aware that folding and rubbing of the prosthesis was foreseeable as a result of capsular contracture and that no warning was given as to this problem. Defendant got more than the evidence supported when the issue of the sufficiency of the warning was submitted to the jury.

Id. at 650-51, 662 P.2d at 650.

In Serna v. Roche Labs, the plaintiff contended that he contracted Stevens-Johnson syndrome as a reaction to a medication proscribed by his doctor. See 101 N.M. at 523, 684 P.2d at 1188. The plaintiff alleged that no warnings were given about the possible dangers of the medication. See id. at 524, 684 P.2d at 1189. The Court of Appeals of New Mexico stated: “This allegation states a theory of liability because, where dangers from use can be anticipated, the manufacturer must provide adequate warnings or the product is defective.” Id., 684 P.2d at 1189 (citing Restatement (Second) of Torts § 402A cmt. h). The Court of Appeals explained that, “[w]here the product is a prescription drug, the manufacturer’s duty to warn is fulfilled if it warns the physician, not the patient.” Serna v. Roche Labs, 101 N.M. at 524, 684 P.2d at 1189. The Court of Appeals stated that the adequacy of a warning to a physician is determined by the following criteria:

1. the warning must adequately indicate the scope of the danger; 2. the warning must reasonably communicate the extent or seriousness of the harm that could result from misuse of the drug; 3. the physical aspects of the warning must be adequate to alert a reasonably prudent person to the danger; 4. a simple directive warning may be inadequate when it fails to indicate the consequences that might result from failure

to follow it and, most importantly, in the context of the present case; 5. the means to convey the warning must be adequate.

Id., 684 P.2d at 1189. The Court of Appeals found that the package insert for the medication and the PDR listing of “Stevens-Johnson Syndrome” in the section on allergic reactions was a prima-facie showing of adequacy. Id. at 525, 684 P.2d at 1190. The plaintiff in Serna v. Roche Labs did not introduce “evidence which would support a factual question as to the adequacy of the warnings.” Id. at 525, 684 P.2d at 1190. The Court of Appeals stated that, if the nonmovant presents evidence of the inadequacy of the warnings, however, “it is improper for the court to grant summary judgment for the drug manufacturer. Here, plaintiff presented no evidence of the inadequacy of the warnings and summary judgment [wa]s proper.” Id., 684 P.2d at 1190. See Ackermann v. Wyeth Pharm., No. 06-41774, 2008 WL 1821379 at *3 n.5 (5th Cir. April 24, 2008)(stating that “the learned-intermediary doctrine is not an affirmative defense. Under Texas law, it delineates to whom a defendant -- usually a prescription drug manufacturer -- owes the duty to warn, but it is not used to show that the plaintiff has no valid case.”).

In Richards v. Upjohn Co., 95 N.M. 675, 625 P.2d 1192 (Ct. App. 1980), the Court of Appeals reversed summary judgment granted for the defendant drug company in a suit arising out of personal injuries suffered by the plaintiff which allegedly resulted from medical treatment by a medication that the defendant manufactured. See id. at 676, 625 P.2d at 1193. The Court of Appeals noted that “[p]roximate cause is a factual issue, unless all facts regarding causation are undisputed or, as a matter of law, there is an independent intervening cause.” Id. at 678, 625 P.2d at 1195. It noted that: “Consequently, unless, as a matter of law, 1) [the defendant]’s warnings are adequate, or 2) [the prescribing doctor]’s failure to consult the appropriate literature before prescribing the [medication] constitutes an independent intervening cause, a genuine issue of

material fact exists and that precludes summary judgment.” Id., 625 P.2d at 1195. The Court of Appeals held that the plaintiff produced circumstantial evidence regarding the cause of the injury he suffered where the defendant had publically acknowledged that the medication could cause deafness that was published in the PDR and the plaintiff demonstrated that he had a dramatic loss of hearing during the period of time he was taking the medication. See id., 625 P.2d at 1195. The Court of Appeals stated that “[i]t is improper for a court on summary judgment proceedings to decide that the warnings of a manufacturer of a drug that is dangerous if misused are adequate as a matter of law if evidence of inadequacy is presented.” Id. at 679, 625 P.2d at 1196. The Court of Appeals also held that “[a] doctor’s negligence is not, as a matter of law, an intervening cause exonerating the drug company, if the doctor’s act is reasonably foreseeable.” Id., 625 P.2d at 1196. The Court of Appeals stated: “Although some courts have held that the inadequacy of a drug company’s warnings cannot be the proximate cause of the patient’s injury when the physician failed to consult the literature or observe the warnings concerning the drug he used, . . . the better reasoned cases do not reach this result.” Richards v. Upjohn Co., 95 N.M. at 681, 625 P.2d at 1198 (internal citations omitted). The Court of Appeals summarized: “The issue, is still the foreseeability of the doctors’ actions. If it was foreseeable that doctors might not consult the PDR or package inserts before using [the medication], a doctor’s failure to do so does not constitute an independent intervening cause relieving a drug company, whose warnings were inadequate, from liability.” Id. at 680, 625 P.2d at 1198.

In Thom v. Bristol-Myers Squibb Co., 353 F.3d 848 (10th Cir. 2003), the Tenth Circuit discussed the learned-intermediary doctrine in Wyoming. See 353 F.3d at 851. The Tenth Circuit noted that “[f]orty-four other jurisdictions have adopted the learned intermediary doctrine in prescription medicine cases.” Id. at 852 (citing Vitanza v. Upjohn Co., 275 Conn. 365, 778 A.2d

829, 838 n.11 (2001)). The Tenth Circuit noted that the Tenth Circuit “ha[d] implied in an analogous case that Wyoming would adopt the doctrine.” Thom v. Bristol-Myers Squibb Co., 353 F.3d at 852. The Tenth Circuit rejected the plaintiffs’ argument that the learned-intermediary doctrine should not be applied because the Wyoming Supreme Court and Legislature and had not specifically adopted the doctrine, “despite a Wyoming district court’s prediction fourteen years ago that [they] would.” Id. The Tenth Circuit explained: “[S]ilence on the part of the state means only that it has not had occasion to review the matter, not that it disagrees with the federal court’s interpretation of state law.” Id. The Tenth Circuit stated:

Although the Wyoming Supreme Court has not to date acknowledged the learned intermediary doctrine, neither has it denied the doctrine; it simply has not ruled on the issue. We can and must safely assume that the delay, in the grandest traditions of all common-law courts, is due to the absence of a well presented and soundly argued case, rather than indicative of some invented implication that the doctrine does not exist.

Id. (internal bracket and quotation marks omitted).

The Supreme Court of Appeals of West Virginia, however, has rejected the learned-intermediary doctrine. See State Ex Rel. Johnson and Johnson Corp. v. Karl, 647 S.E.2d at 913. In State Ex Rel. Johnson and Johnson Corp. v. Karl, the court explained that the learned-intermediary doctrine “provides an exception to the general rule imposing a duty on manufacturers to warn consumers about the risks of their products.” 647 S.E.2d at 902 (internal quotation marks omitted). The court stated that the learned-intermediary doctrine “stands for the proposition that a drug manufacturer is excused from warning each patient who receives the product when the manufacturer properly warns the prescribing physician of the product’s dangers.” Id. at 902-903. The court stated that “[s]ome authorities have suggested that the number of jurisdictions having adopted the doctrine is an overwhelming majority . . . [but that it’s o]wn research has yielded a

markedly different result.” Id. at 903. The court found that “a mere twenty-one states have expressly adopted the learned intermediary doctrine.” Id. New Mexico was not among the states that the court found had expressly adopted the learned-intermediary doctrine. See id. at n.6. The court stated that “the highest courts of the remaining twenty-two states, . . . [including] New Mexico, . . . have not adopted the learned intermediary doctrine.” Id. at 905. “Thus, while the doctrine is widely applied among lower courts, the number of high courts who have followed suit and expressly adopted the doctrine, while admittedly in the majority, do not make up the overwhelming majority that has often been suggested by courts and commentators.” Id. (emphasis in original). The court noted that:

Among the primary justifications that have been advanced for the learned intermediary doctrine are (1) the difficulty manufacturers would encounter in attempting to provide warnings to the ultimate users of prescription drugs; (2) patients' reliance on their treating physicians' judgment in selecting appropriate prescription drugs; (3) the fact that it is physicians who exercise their professional judgment in selecting appropriate drugs; (4) the belief that physicians are in the best position to provide appropriate warnings to their patients; and (5) the concern that direct warnings to ultimate users would interfere with doctor/patient relationships.

Id. The court stated it found “these justifications for the learned intermediary doctrine to be largely outdated and unpersuasive.” Id. at 906. The court noted that the doctrine dated to 1925. See id. The court explained that:

Significant changes in the drug industry have post-dated the adoption of the learned intermediary doctrine in the majority of states in which it was followed. We refer specifically to the initiation and intense proliferation of the direct-to-consumer advertising, along with its impact on the physician/patient relationship, and the development of the internet as a common method of dispensing and obtaining prescription drug information.

Id. at 907. “Consumer-directed advertising of pharmaceuticals thus belies each of the premises on which the learned intermediary doctrine rests.” Id. at 910. The court quoted Edwards v. Basel Pharmacies, 116 F.3d 1341 (10th Cir. 1997), stating that:

When all of its premises are absent, as when direct warnings to consumers are mandatory, the learned intermediary doctrine, “itself an exception to the manufacturer’s traditional duty to warn consumers directly of the risk associated with any product, simply drops out of the calculus, leaving the duty of the manufacturer to be determined in accordance with general principles of tort law.”

State Ex Rel. Johnson and Johnson Corp. v. Karl, 647 S.E.2d at 911 (quoting Edwards v. Basel Pharm., 116 F.3d at 1343 (discussing the adequacy of warnings for nicotine patches under Texas law). The court stated : “Given the plethora of exceptions to the learned intermediary doctrine, [it] ascertain[ed] no benefit in adopting a doctrine that would require the simultaneous adoption of numerous exceptions in order to be justly utilized.” State Ex Rel. Johnson and Johnson Corp. v. Karl, 647 S.E.2d at 913.

In Porter v. Eli Lilly and Company, No. 1:06-cv-1297-JOF (N.D. Ga. February 25, 2008), the plaintiff asked the district court to “take judicial notice of Lilly’s website www.prozac.com as evidence that Prozac had been extensively advertised in the media and therefore § 6(d)(2) [of the Restatement (Third) of Torts] would require a consumer warning.” No. 1:06-cv-1297-JOF at 17 (“Porter Opinion”). The district court noted that “this would be an expansion of the current state of law as it exists in Georgia which affirmatively recognizes the learned intermediary doctrine.” Id. The district court stated that “[t]he Supreme Court of Georgia’s citation to § 6(d)(1) -- which is unrelated to direct notification to consumers issue -- is not a sufficient basis upon which this court could conclude that Georgia would now adopt the suggestions of the Restatement (Third), reject the learned intermediary doctrine, and require direct warning to consumers.” Porter Opinion at 17. The district court found that the plaintiff’s assertion that Eli Lilly was “responsible for the suicide of her husband . . . because [it] failed to adequately warn of the risks involving Prozac and suicide,” id. at 3, could not establish proximate cause, because “no matter what might have been presented as a warning with Prozac in terms of increased suicide risk, this would not have impacted [the doctor’s]

decision-making because he did not view [the decedent] as a suicide risk,” id. at 25. Eli Lilly was entitled to summary judgment, because “[t]here was no evidence in [the proscribing doctor’s] deposition testimony that a different warning on Prozac would have impacted [the proscribing doctor’s] decision to prescribe Prozac.” Id. at 25, 25.

In Giles v. Wyeth, Inc., 500 F.Supp.2d 1063 (S.D.Ill. 2007), the district court noted: “Some states apply a heeding presumption in learned intermediary cases. In these states, a court presumes that warnings, if given, will be heeded and followed and that medical practitioners will act competently.” Id. at 1065-66. In Tobin v. Smithkline Beecham Pharmaceuticals, No. 00-CV-0025-Bea (D. Wyo. 2001), the district court stated its “review of recent Wyoming case law and legislation to date provide[d] nothing to indicate that the Wyoming Supreme Court would not adopt the learned intermediary doctrine.” Exhibit 13 to Response, Tobin v. Smithkline Beecham Pharmaceuticals, No. 00-CV-0025-Bea (D. Wyo. 2001), Order Denying Smithkline Beecham Corporation’s Motion for Summary Judgment at 9 (“Tobin Order”). The district court then stated “in cases, such as this where the adequacy of the warning has not been demonstrated, the presumption created by comment j [to Section 402A of the Second Restatement of Torts presuming that a consumer would have read and heeded any warning the manufacture provided] can operate as a presumption of causation.” Id. at 15-16 (internal quotation marks omitted). The district court also noted that “[u]nder the law of product liability there exists a presumption [that] a consumer will heed a proper warning.” Id. at 18 (citing Restatement (Second) of Torts § 402A cmt. j).

The learned-intermediary doctrine is inapplicable where there has been a failure to warn. See Thom v. Bristol-Myers Squibb Co., 353 F.3d 848, 853 (10th Cir. 2003)(stating that “[p]hysicians become learned intermediaries only when they have received adequate warnings from the drug manufacturer.”). In McNeil v. Wyeth, 462 F.3d 364 (5th Cir. 2006), the United States Court of

Appeals for the Fifth Circuit noted that:

Although [the defendant drug manufacturer]'s label mentions the conditions of which [the plaintiff] complains, [the plaintiff]'s claim. . . is not that the warning is inadequate because her condition was not mentioned. Rather, her argument is that the label is misleading as to the risk level for developing the condition. We are aware of no Texas case allowing adequacy as a matter of law in such situations, and therefore we apply the default Texas rule that adequacy questions go to the jury.

Id. at 368.

2. Proximate Cause of an Injury.

Under New Mexico law, “[i]f, in light of all the circumstances of this case, [an adequate warning] [adequate directions for use] would have been noticed and acted upon to guard against the danger, a failure to give [an adequate warning] [adequate directions for use] is a cause of injury.” N.M.R.A., Civ. UJI 13-1425 (brackets in original). New Mexico Uniform Jury Instruction No. 13-1424 instructs that “[w]ith the exception of proximate cause in warning cases, treated separately under UJI 13-1425, the general tort law definition of proximate cause is applicable in products liability cases. The first paragraph of this instruction is UJI 13-308 and the comment to that instruction is applicable.” N.M.R.A., Civ. UJI 13-1424, cmt. See Weitz v. Lovelace, Health Sys., Inc., 214 F.3d 1175, 1182 (10th Cir. 2000)(“In the products liability context, New Mexico has evidenced its agreement with the common-sense proposition that a duty to warn does not arise where the danger is known.”)(citing Perfetti v. McGhan Med., 99 N.M. at 650, 662 P.2d at 651 (“In this case there would be no duty to warn the [victim] if he actually knew of the danger.”))).

Under New Mexico law, the adequacy of warnings are usually a question of fact. See, e.g., Wilchinsky v. Medina, 108 N.M. 511, 516, 775 P.2d 713, 718 (1989)(“The timing and adequacy of any warnings, if given, are fact questions for the jury to decide in order to determine the proportionate fault, if any, of the physician.”); Michael v. Warner/Chilcott, 91 N.M. 651, 655, 579

P.2d 183, 187 (Ct. App. 1978)(“In reversing the case, we held that adequacy of the warning given by a manufacturer in a negligence action presents an issue of fact for the jury. In making this determination, we said: ‘The warning must adequately indicate the scope of the danger.’”)(quoting First Nat. Bank in Albuquerque v. Nor-Am Agr. Products, Inc., 88 N.M. 74, 83-84, 537 P.2d 682, 691 (Ct. App. 1975)). As the Court of Appeals of New Mexico stated in Perfetti v. McGhan Medical:

Defendant's claim is based on the surgeon's general knowledge of the danger of deflation and that deflation could occur at any time. This mistakes the danger involved and, thus, the warning that was required. Defendant's duty was to warn of the nature and extent of the danger of a leak developing because of wear of the prosthesis at a fold resulting from capsular contracture. There was a factual question for the jury as to the surgeon's knowledge of this danger; the trial court could not have properly ruled on the surgeon's knowledge as a matter of law.

99 N.M. at 651, 662 P.2d at 650.

The Tenth Circuit has granted summary judgment under similar circumstances in which the plaintiff could not prove that an alleged failure to warn proximately caused the injury. See, e.g., Eck v. Parke, Davis and Co., 256 F.3d 1013, 1025 (10th Cir. 2001)(“The [plaintiffs] are, in turn, unable to establish that the alleged failure to warn of the possible adverse reactions between the drugs was the proximate cause of [plaintiff’s] injuries. Accordingly, we affirm the district court’s grant of summary judgment to defendants.”). Courts in other jurisdictions have held that, in the context of prescription-drug-failure-to-warn cases, a manufacturer’s alleged failure to warn cannot be said to be the proximate cause of injury if the prescribing physician had independent knowledge of the risk at issue. See, e.g., Odom v. G.D. Searle and Co., 979 F.2d 1001, 1003 (4th Cir. 1992)(“Even viewing the facts most favorably to [the plaintiff], we cannot escape the district court's conclusion that [the doctor] would have prescribed the [medication] no matter how carefully [the defendant] refined the phrasing of its warning.”); Plummer v. Lederle Lab., 819 F.2d 349, 351, 358-59 (2d Cir.

1987)(holding that, as a matter of law, there could be no proximate cause when the physician testified that, at the time he vaccinated plaintiff's granddaughter, he knew of the information about the risks of contact polio that plaintiff claimed should have been included in the vaccine's package insert); Kirsch v. Picker Intern., Inc., 753 F.2d 670, 674 (8th Cir. 1985)(noting that, even if manufacturer failed to warn physician of risks associated with use of x-ray equipment, that failure could not be the cause of the patient's injuries where the physician already was aware of the risks); Stanback v. Parke Davis and Co., 657 F.2d 642, 645 (4th Cir. 1981)(upholding summary judgment on plaintiff's failure to warn claim where the treating physician testified that he knew of the risk of Guillain-Barre Syndrome associated with the flu vaccine, Fluogen, at the time he vaccinated the plaintiff, but that he had not found it necessary, and did not make it his practice, to advise patients about the risks associated with flu vaccinations); Hall v. Merck, Sharp and Dohme, 774 F. Supp. 604, 607 (D. Kan. 1991)(explaining that, "[w]here it is uncontroverted that the prescribing physician is aware of the risks associated with a drug, courts have consistently held that a drug manufacturer is entitled to summary judgment."); Wash. St. Physicians' Ins. v. Fisons Corp., 858 P.2d 1054, 1062 (Wash. 1993)(noting that the manufacturer's failure to warn cannot be the proximate cause of the patient's injury if the physician was already aware of the risk involved in the use of the drug); Mowery v. Crittenton Hosp., 400 N.W.2d 633, 638 (Mich. App. 1986)(stating that the manufacturer was entitled to summary judgment because, although the prescribing physician testified that she was aware of the risk of retinal detachment from having read the medical literature, she "stated that it was worth taking the 'risks' to avoid repeated intraocular lens dislocation, endangering plaintiff's cornea. Thus, it appears that even if [the doctor] had been given additional warnings by defendants of the risk of retinal detachment, she would have chosen to prescribe [the medication] for plaintiff. There is no evidence that she would have done otherwise.").

Courts have also held that a prescription-drug manufacturer's alleged failure to warn a prescribing physician cannot be the proximate cause of injury unless the plaintiff can establish that a different warning would have changed the physician's decision to prescribe the drug, i.e., that, but for the alleged inadequate warning, the physician would not have prescribed the product. See, e.g., Wheat v. Pfizer, Inc., 31 F.3d 340, 343 (5th Cir. 1994)(holding that the "[p]laintiffs must demonstrate that 'a proper warning would have changed the decision of the treating physician, i.e., that but for the inadequate warning, the treating physician would not have used or prescribed the product.'")(quoting Willett v. Baxter Int'l, Inc., 929 F.2d 1094, 1099 (5th Cir. 1991)); Odom v. G.D. Searle and Co., 979 F.2d at 1003-1004 (upholding summary judgment where the prescribing physician testified that a different warning would not have changed his decision to prescribe an intrauterine device); Plummer v. Lederele Labs., 819 F.2d at 358 (holding that there was no proximate cause in absence of evidence that different warning would have caused physician to act differently); Fisher v. Bristol-Myers Squibb Co., 181 F.R.D. 365, 370 (N.D. Ill. 1998)("In a prescription drug failure to warn case, the plaintiff must establish that an adequate warning would have convinced the treating physician not to prescribe the product for the plaintiff")(internal quotation marks omitted); In re Norplant Contraceptive Prods. Liab. Litig., 955 F. Supp. 700, 710 (E.D. Tex. 1997)(stating that the plaintiffs have the burden of proving that a different warning would have changed the decision of the prescribing physician); Krasnopsky v. Warner-Lambert Co. 799 F. Supp. 1342, 1347 (E.D.N.Y. 1992)(noting that any alleged inadequacy of the manufacturer's warning was not, as a matter of law, the proximate cause of the plaintiff's injuries where the physician testified he would have prescribed the drug even if the warnings had been different); Windham v. Wyeth Lab., Inc., 786 F. Supp. 607, 612 (S.D. Miss. 1992)(granting summary judgment on failure to warn claim where the prescribing physician testified that he still would have prescribed

a medication even if he had received additional information); Thomas v. Hoffman-La Roche, Inc., 731 F. Supp. 224, 229 (N.D. Miss. 1989)(“A plaintiff in a prescription drug products liability case has the burden of proving that an adequate warning to the prescribing physician would have altered the physician’s conduct.”); Mascarenas v. Union Carbide Corp., 492 N.W.2d 512, 517 (Mich. App. 1992)(stating that, “[t]o establish a prima facie case that a manufacturer's breach of its duty to warn was a proximate cause of an injury sustained, a plaintiff must present evidence that the product would have been used differently had the warnings been given.”); Vaughn v. G.D. Searle and Co., 536 P.2d 1247, 1250-51 (Or. 1975)(holding that, where a different warning would not have changed doctor’s behavior, the plaintiff could not establish proximate cause).

There are exceptions to the learned-intermediary doctrine. Restatement (Third) of Torts § 6(d) provides:

(d) A prescription drug or medical device is not reasonably safe due to inadequate instructions or warnings if reasonable instructions or warnings regarding foreseeable risks of harm are not provided to:

- (1) prescribing and other health-care providers who are in a position to reduce the risks of harm in accordance with the instructions or warnings; or
- (2) the patient when the manufacturer knows or has reason to know that health-care providers will not be in a position to reduce the risks of harm in accordance with the instructions or warnings.

Restatement (Third) of Torts § 6(d)(1)-(2). The Supreme Court of New Mexico has cited to the Restatement (Third) of Torts. See, e.g., Baldonado v. El Paso Nat’l Gas Co., 2008-NMSC-005, ¶ 14, 176 P.3d 277, 281; Payne v. Hall, 2006-NMSC-029, ¶ 14, 137 P.3d 599, 604; Berlangieri v. Running Elk Corp., 2003-NMSC-024, ¶ 18, 76 P.3d 1098, 1104. The Supreme Court of New Mexico has not expressly adopted or cited Restatement (Third) of Torts § 6(d). See Defendant Eli Lilly and Company’s Reply in Support of its Motion for Summary Judgment on All Claims at 12,

filed May 12, 2008 (Doc. 88)(“Reply”); Response at 12 n.11. Comment e to § 6 of the Restatement (Third) of Torts provides:

e. Direct warnings to patients. Warnings and instructions with regard to drugs or medical devices that can be sold legally only pursuant to a prescription are, under the “learned intermediary” rule, directed to health-care providers. Subsection (d)(2) recognizes that direct warnings and instructions to patients are warranted for drugs that are dispensed or administered to patients without the personal intervention or evaluation of a health-care provider. An example is the administration of a vaccine in clinics where mass inoculations are performed. In many such programs, health-care providers are not in a position to evaluate the risks attendant upon use of the drug or device or to relate them to patients. When a manufacturer supplies prescription drugs for distribution to patients in this type of unsupervised environment, if a direct warning to patients is feasible and can be effective, the law requires measures to that effect.

Although the learned intermediary rule is generally accepted and a drug manufacturer fulfills its legal obligation to warn by providing adequate warnings to the health-care provider, arguments have been advanced that in two other areas courts should consider imposing tort liability on drug manufacturers that fail to provide direct warnings to consumers. In the first, governmental regulatory agencies have mandated that patients be informed of risks attendant to the use of a drug. A noted example is the FDA requirement that birth control pills be sold to patients accompanied by a patient package insert. In the second, manufacturers have advertised a prescription drug and its indicated use in the mass media. Governmental regulations require that, when drugs are so advertised, they must be accompanied by appropriate information concerning risk so as to provide balanced advertising. The question in both instances is whether adequate warnings to the appropriate health-care provider should insulate the manufacturer from tort liability.

Those who assert the need for adequate warnings directly to consumers contend that manufacturers that communicate directly with consumers should not escape liability simply because the decision to prescribe the drug was made by the health-care provider. Proponents of the learned intermediary rule argue that, notwithstanding direct communications to the consumer, drugs cannot be dispensed unless a health-care provider makes an individualized decision that a drug is appropriate for a particular patient, and that it is for the health-care provider to decide which risks are relevant to the particular patient. The Institute leaves to developing case law whether exceptions to the learned intermediary rule in these or other situations should be recognized.

When the content of the warnings is mandated or approved by a governmental agency regulation and a court finds that compliance with such regulation federally preempts tort liability, then no liability under this Section can attach.

Restatement (Third) of Torts § 6 cmt. e.

NEW MEXICO LAW REGARDING INTERVENING CAUSE

Under New Mexico law, an intervening force may interrupt the chain of causation and thereby supersede the original alleged negligence, product defect, or other grounds for liability, and relieve the defendant of liability. See Johnstone v. City of Albuquerque, 2006-NMCA-119, ¶ 21, 145 P.3d 76, 83. “Contributory negligence and independent intervening cause are questions for the jury, unless, as a matter of law, there is no evidence upon which to submit the issue to the jury.” City of Belen v. Harrell, 93 N.M. 601, 604, 603 P.2d 711, 714 (1979). “An intervening force is a superseding cause if the intervening force was not foreseeable at the time of the primary negligence.” Johnstone v. City of Albuquerque, 2006-NMCA-1191, ¶ 21, 145 P.3d at 83.

New Mexico law identifies suicide as an independent intervening cause that absolves a defendant of liability. See, e.g., City of Belen v. Harrell, 93 N.M. 601, 604, 603 P.2d 711, 714 (1979). In New Mexico, suicide is a voluntary, deliberate, and intentional act of self-destruction by someone of sound mind. See Solorzano v. Bristow, 2004-NMCA-136, ¶ 14, 103 P.3d 582, 586. “The voluntary, willful act of suicide is a new or intervening agency that breaks the chain of causation.” Johnstone v. City of Albuquerque, 2006-NMCA-119, ¶ 22, 145 P.3d at 83. Consequently, where the record reveals such a deliberate, intentional act of suicide, summary judgment is appropriate because proximate causation cannot be proven. See id., ¶ 28, 145 P.3d at 85.

In Johnstone v. City of Albuquerque, the Court of Appeals of New Mexico rejected the claim that the decedent’s stepfather was responsible for her suicide because the decedent used his gun and he was a police officer. See 2006-NMCA- 119, ¶¶ 1-2, 145 P.3d at 78. The Court of Appeals stated:

When an individual commits suicide using a gun owned by someone else, the owner of the gun is not liable for the death under settled negligence principles. In the absence of intentional conduct that creates the risk of suicide, or a legally recognized

special relationship and knowledge of a specific likelihood of harm that gives rise to a duty to avoid harm, suicide operates as an independent intervening cause of death. In this case, we decline Plaintiff's invitation to abrogate this long-standing precedent. Defendant's sixteen year-old stepdaughter used his firearm to commit suicide. Her estate sued him individually, together with his employer the City of Albuquerque, alleging that Defendant was grossly negligent in leaving his firearm unattended. Summary judgment was entered for Defendant in his individual capacity, dismissing Plaintiff's suit. We affirm.

Id. ¶ 1, 145 P.3d at 78. The Court of Appeals noted: “Courts generally decline to impute a duty to the defendant when he neither caused the decedent's uncontrollable suicidal impulse nor had custody of the decedent and knowledge of her suicidal ideation.” Id. ¶ 10, 145 P.3d at 81 (internal quotation marks omitted).

There are two exceptions to this general rule. See id. ¶ 11, 145 P.3d at 81. One is when the actor's tortious conduct “induces a mental illness in the decedent from which the death results.” Id., 145 P.3d at 81. The other is when there is a duty that results “from a special relationship between the decedent and the defendant, that presumes or includes knowledge of the decedent's risk of suicide.” Id., 145 P.3d at 81. The Court of Appeals noted that “special relationships are set forth in the Restatement (Second) of Torts §§ 314A, 315-319 (1999).” Id., 145 P.3d at 81. The Court of Appeals found that neither exception was applicable to the facts in Johnstone v. City of Albuquerque. See 2006-NMCA-119, ¶ 12, 145 P.3d at 81. The Court of Appeals rejected the argument that the defendant had a special relationship with the decedent because “New Mexico has not found such a special relationship to exist between parent and child.” Id. ¶ 15, 145 P.3d at 82. The Court of Appeals distinguished the relationship between a mental health professional and a patient and the relationship between a parent and child, because of the professional's “knowledge of the patient, a layperson could not reasonably be expected to anticipate the mental health consequences of their acts or omissions.” Id., 145 P.3d at 82.

In Solorzano v. Bristow, 2004-NMCA-136, 103 P.3d 582, the Court of Appeals of New Mexico held that a specific duty could exist between a decedent and a defendant who had directly observed the decedent's behavior. See 2004-NMCA, ¶ 21, 103 P.3d at 587. The decedent in Solorzano v. Bristow began acting erratically while her mother, the defendant, drove. See id. ¶¶ 2-5, 145 P.3d at 583-84. The decedent "either fell or jumped from a van being driven by [the d]efendant." Id. ¶ 2, 103 P.3d at 583. The Court of Appeals would not "indulge" a presumption in favor of suicide because the decedent "fell from the vehicle without any intervention from anyone else." Id. ¶ 16, 103 P.3d at 586. The Court of Appeals held, on the facts presented in Solorzano v. Bristow that the harm to the decedent was foreseeable. See id. ¶ 21, 103 P.3d at 587.

NEW MEXICO LAW REGARDING STRICT LIABILITY

New Mexico had adopted the basis for products liability found in Restatement (Second) of Torts § 402A (1965). See Serna v. Roche Labs., 101 N.M. at 523, 684 P.2d at 1188.

The policy underpinnings supporting imposition of strict liability on product manufacturers and suppliers include (1) ensuring that the risk of loss for injury resulting from defective products is borne by the suppliers, principally because they are in a position to absorb the loss by distributing it as a cost of doing business; (2) encouraging suppliers to select reputable and responsible manufacturers who generally design and construct safe products and who generally accept financial responsibility for injuries caused by their defective products; and (3) promoting fairness by ensuring that plaintiffs injured by an unreasonably dangerous product are compensated for their injuries.

Smith ex rel. Smith v. Bryco Arms, 2001-NMCA-090, ¶ 12, 33 P.3d 638, 644 (internal quotation marks omitted). The Supreme Court of New Mexico explained in Brooks v. Beech Aircraft Corp., 120 N.M. 372, 902 P.2d 54 (1995) that:

The policy of risk- or cost-distribution continues to serve as a primary basis for imposing strict products liability. . . . In addition to the cost-distribution rationale . . . other courts have approved specifically the rationale that imposing strict liability relieves plaintiffs of the burden of proving ordinary negligence under circumstances in which such negligence is likely to be present but difficult to prove. . . . The third

policy cited for the imposition of strict liability is that suppliers who otherwise might not be liable because of a passive role in the chain of supply should be encouraged to select reputable and responsible manufacturers who generally design and construct safe products and who generally accept financial responsibility for injuries caused by their defective products. . . . Fourth and finally, imposing strict products liability serves the interests of fairness. . . . The fairness rationale embodies a normative judgment that plaintiffs injured by an unreasonably dangerous product should be compensated for their injuries. At the heart of this judgment lies the conclusion that although the manufacturer has provided a valuable service by supplying the public with a product that it wants or needs, it is more fair that the cost of an unreasonable risk of harm lie with the product and its possibly innocent manufacturer than it is to visit the entire loss upon the often unsuspecting consumer who has relied upon the expertise of the manufacturer when selecting the injury-producing product.

Id. at 375-76, 902 P.2d at 57-58 (internal citations omitted).

To succeed on a cause of action brought under a theory of strict products liability, a plaintiff must prove five elements: (i) the product was defective; (ii) the product was defective when it left the hands of the defendant and was substantially unchanged when it reached the use or consumer; (iii) that because of the defect the product was unreasonably dangerous to the use or consumer; (iv) the consumer was injured or was damaged; and (v) the defective condition of the product was the proximate cause of the injury or damage. See Armeanu v. Bridgestone/Firestone North Am. Tires, L.L.C., No. CIV-05-619 JB/DJS., 2006 WL 4060666 at *3 (D.N.M. September 26, 2006)(Browning, J.). Proximate cause is a required element in a strict liability cause of action. Id. at *7.

Proof of a defect is required to succeed on a strict products liability claim under New Mexico law. See Perfetti v. McGhan Med., 99 N.M. at 653, 662 P.2d at 654. The Court of Appeals explained in Perfetti v. McGhan Med. that, pursuant to comment h to § 402A of the Restatement (Second) of Torts, where the seller “has reason to anticipate the danger that may result from a particular use . . . he may be required to give adequate warning of the danger . . . and a product sold without such warning is in a defective condition.” 99 N.M. at 650, 662 P.2d at 649 (internal quotation marks omitted). The defendant contended that the prosthesis fell within the category of “unavoidably

unsafe products” discussed in comment k to § 402A of the Restatement (Second). Id., 662 P.2d at 649. The Court of Appeals explained that these category of products are those “which, in the present state of human knowledge, are quite incapable of being made safe for their intended and ordinary use.” Id., 662 P.2d at 649 (internal quotation marks omitted).

New Mexico courts have recognized that the theory of products liability is applicable to three defects: design, manufacturing, and marketing (warnings). See Morales v. E.D. Etnyre and Co., 382 F.Supp. 2d 1252, 1264 (D.N.M. 2005) (Browning, J)(citing Smith v. Bryco Arms, 2001-NMCA-090, ¶ 8, 33 P.3d 638, 643 and Fernandez v. Ford Motor Co., 118 N.M. 100, 109, 879 P.2d 101, 110 (Ct.App.1994)). To recover under the strict liability theory, a plaintiff must prove that a defect in the product as manufactured, designed, or marketed created an unreasonably dangerous risk of injury. In the context of pharmaceutical cases, New Mexico courts have adopted comment k to § 402A of the Restatement (Second) of Torts. See Hines v. St. Joseph’s Hosp., 86 N.M. 763, 764, 527 P.2d 1075, 1076 (Ct.App. 1974).

In Hines v. St. Joseph’s Hospital, the plaintiff received a blood transfusion and later began treatment for what her doctor diagnosed as most likely a serum hepatitis. See 86 N.M. at 764, 527 P.2d at 1076. The Court of Appeals noted that New Mexico has adopted the rule of strict liability stated in Restatement (Second) of Torts. See 86 N.M at 764, 527 P.2d at 1076. The Court of Appeals explained that, in comment k, there is an exception to the rule for unavoidably unsafe products. See 86 N.M at 764, 527 P.2d at 1076. The Court of Appeals quoted the Restatement (Second) of Torts:

“There are some products which, in the present state of human knowledge, are quite incapable of being made safe for their intended and ordinary use. These are especially common in the field of drugs. An outstanding example is the vaccine for the Pasteur treatment of rabies, which not uncommonly leads to very serious and damaging consequences when it is injected. Since the disease itself invariably leads to a dreadful death, both the marketing and the use of the vaccine are fully justified, notwithstanding the unavoidable high degree to risk which they involve. Such a

product, properly prepared, and accompanied by proper directions and warning, is not defective, nor is it unreasonably dangerous. The same is true of many other drugs, vaccines, and the like, many of which for this very reason cannot legally be sold except to physicians, or under the prescription of a physician. It is also true in particular of many new or experimental drugs as to which, because of lack of time and opportunity for sufficient medical experience, there can be no assurance of safety, or perhaps even of purity of ingredients, but such experience as there is justifies the marketing and use of the drug notwithstanding a medically recognizable risk. The seller of such products, again with the qualification that they are properly prepared and marketed, and proper warning is given, where the situation calls for it, is not to be held to strict liability for unfortunate consequences attending their use, merely because he has undertaken to supply the public with an apparently useful and desirable product, attended with a known but apparently reasonable risk.”

Hines v. St. Joseph’s Hosp., 86 N.M. at 764, 527 P.2d at 1076 (quoting Restatement (Second) of Torts cmt. k). The Court of Appeals explained that, at the time of the plaintiff’s transfusion, no test could adequately detect the hepatitis virus in blood. See Hines v. St. Joseph’s Hosp., 86 N.M. at 764, 527 P.2d at 1076. The Court of Appeals further explained that no process could destroy the virus without damaging the blood, and thus, the blood was a product incapable of being made safe for its intended and ordinary use. See id., 527 P.2d at 1076. The Court of Appeals nonetheless stated that the risk of the blood being infected is outweighed by the public benefit of saving life, and thus is a reasonable risk. See id. at 765, 527 P.2d at 1076. The Court of Appeals noted that “[o]rdinarily the manufacturer’s duty to warn of the dangers of prescription drugs is to the attending physician, not the patient.” Id., 527 P.2d at 1076. The Court of Appeals found that summary judgment was appropriate for the blood-provider defendant, because “Blood Services placed a warning on the blood container and also ‘constantly distributed’ an ‘Official Circular of Instructions for Use’ to the hospital staff. [The doctor]. . . who gave the transfusion, stated he knew of the danger of hepatitis transmission in blood transfusions. Blood Services’ warning was adequate.” Id., 527 P.2d at 1076.

In Jones v. Minnesota Mining and Manufacturing Co., 100 N.M. 268, 669 P.2d 744 (Ct. App. 1983), the Court of Appeals observed:

Prescription drugs are likely to be complex medicines, esoteric in formula and varied in effect. As a medical expert, the prescribing physician can take into account the propensities of the drug, as well as the susceptibilities of his patient. His is the task of weighing the benefits of any medication against its potential dangers. The choice he makes is an informed one, an individualized medical judgment bottomed on a knowledge of both patient and palliative. Pharmaceutical companies then, who must warn ultimate purchasers of dangers inherent in patent drugs sold over the counter, in selling prescription drugs are required to warn only the prescribing physician, who acts as a learned intermediary between manufacturer and consumer.

100 N.M. at 284-85, 669 P.2d 760-61 (internal quotation marks omitted). The Court of Appeals explained: “A warning, to be adequate, must disclose the nature and extent of the danger. . . . The knowledge that equates to this warning must be knowledge of the nature and extent of the danger.”

(internal citation omitted). The Court of Appeals observed:

Comment k thus provides what could serve either as a door leading to escape from strict liability or a trap door leading to the downfall of the unwary manufacturer. The key to the door which [the defendant] should have taken and which would have prevented the damage suffered by these plaintiffs is in the form of warnings. The assertion of liability in this case hinges on the warning which the manufacturer who wishes to avoid liability for an unavoidably unsafe product must provide and which [the defendant] chose to avoid.

Id. at 284, 669 P.2d at 760. See Graham by Graham v. Wyeth Labs, 906 F.2d 1399, 1405 (10th Cir. 1990)(stating that comment k to § 402A of the Restatement (Second) of Torts immunity is viewed as a defense).

“An unreasonable risk of injury is a risk which a reasonably prudent person having full knowledge of the risk would find unacceptable.” Smith ex rel. Smith v. Bryco Arms, 2001-NMCA-090, ¶ 13, 33 P.3d at 644. “Determining whether a product design poses an unreasonable risk of injury also involves considering whether the risk can be eliminated without seriously impairing the usefulness of the product or making it unduly expensive.” Id., 33 P.3d at 644. “Whether a product is unreasonably dangerous, and therefore defective, is ordinarily a question for the jury.” Id. ¶ 14, 33 P.3d at 644.

The jury instructions covering strict products liability are designed to encourage a risk-benefit calculation by defining unreasonable risk of injury in a way which requires the jury to balance meritorious choices for safety made by the manufacturer while minimizing the risk that the public will be deprived needlessly of beneficial products.

Id., 33 P.3d at 644 (internal quotation marks omitted).

LAW REGARDING NEGLIGENCE PER SE

To establish a negligence per-se claim, a plaintiff must prove: (i) that there is a statute which prescribes certain actions or defines a standard of conduct, either explicitly or implicitly; (ii) that the defendant violated the statute; (iii) that the plaintiff must be in the class of persons that the statute seeks to protect; and (iv) that the harm or injury to the plaintiff must generally be of the type the legislature, through the statute, sought to prevent. See Johnstone v. City of Albuquerque, 2006-NMCA-119, ¶ 16, 145 P.3d at 82. To hold a defendant liable under a claim of negligence per se, the defendant must be shown to have violated a specific statute. See Parker v. E. I. DuPont deNemours and Co., Inc., 121 N.M. at 132, 909 P.2d at 12. New Mexico Uniform Civil Jury Instruction UJI 13-1501 provides:

There [was a] [were] statute[s] in force in this state, at the time of the occurrence in question, which provided that:

(Quote or paraphrase the applicable part of the statute in question. If more than one statute is in question, list each statute separately)

If you find from the evidence that _____ (party) violated [this] [any one of these] statute[s], then _____'s conduct constitutes negligence as a matter of law, [unless you further find that such violation was excusable or justified].

[To legally justify or excuse a violation of a statute, the violator must sustain the burden of showing that [s]he did that which might reasonably be expected of a person of ordinary prudence, acting under similar circumstances, who desired to comply with the law.]

N.M.R.A. Civ. UJI 13-1501. This instruction appears in Chapter Fifteen, Statutes and Ordinances,

not Chapter Sixteen, Tort Law -- Negligence. The “Directions for Use” for N.M.R.A., Civ. UJI 13-1501 notes that “UJI 13-1503 should be used in addition to this instruction when there is an issue of proximate cause.” N.M.R.A., Civ. UJI 13-1501, Directions for Use. N.M.R.A., Civ. UJI 13-1503 provides:

Negligence resulting from a violation of a[n] [statute] [or] [ordinance] is no different in effect from that resulting from other acts or omissions constituting negligence. In each case the negligence is of no consequence unless it was a cause of or contributed to, an injury found by you to have been suffered by the plaintiff.

N.M.R.A., Civ. UJI 13-1503.

Private litigants cannot enforce the Federal Food, Drug and Cosmetic Act through private actions. See Cottrell Ltd. v. Brotrol Int’l Inc., 191 F.3d 1248, 1255 (10th Cir. 1999)(stating that “claims that require direct interpretation and application of the FDCA are not properly recognized because such matters are more appropriately addressed by the FDA, especially in light of Congress’s intention to repose in that body the task of enforcing the FDCA.”)(quoting Braintree Labs., Inc. v. Nephro-Tech, Inc., No. 96-2459-JWL, 1997 WL 94237 at *6 (D.Kan. February 26, 1997)). Similarly, “the determination whether labeling revisions are necessary is, in the end, squarely and solely FDA’s.” 71 Fed. Reg. 3934. Ultimately, it is up to the FDA to determine whether its regulations have been violated and, if so, what should be done about it. 71 Fed. Reg. 3968 states:

The statutory and regulatory requirements for the submission of information to FDA are accompanied by statutory provisions addressing the failure of a sponsor to comply with these requirements. A manufacturer that introduces a new drug into interstate commerce without having submitted the required premarket information has violated the act (section 505(a) of the act) and is subject to FDA enforcement action. Similarly, if a manufacturer fails to submit information required by 21 CFR 314.80 and 314.81, it is subject to enforcement action under 21 U.S.C. 331(e). FDA is authorized to investigate suspected fraud using its general statutory investigative authority (section 702 of the act (21 U.S.C. 372)). The agency is also empowered to address fraud by seeking injunctive relief and civil penalties (21 U.S.C. 332, 333(g)(1)(A)), and has authority to invoke the general federal prohibition on making false statements to the

Federal Government (18 U.S.C. 1001). In sum, FDA has a variety of enforcement options that allow it to make a calibrated response to suspected violations of the act's information submission requirements.

71 Fed. Reg. 3968.

On the other hand, under New Mexico law, the Federal Food Drug and Cosmetic Act and its regulations and statutes do not change the common law duty to warn, but “merely set minimal standards.” Michael v. Warner/Chilcott, 91 N.M. at 654, 579 P.2d at 186 (stating that “[t]he Defendant still owes a duty to warn of dangers of which it knew or should have known in the exercise of reasonable care.”)(internal quotation marks omitted). See Parker v. E.I. Du Point de Nemours and Co., Inc., 121 N.M. at 131, 909 P.2d at 12 (holding that summary judgment was appropriately granted for the defendant when the plaintiffs alleged a claim for negligence per se based on the defendant’s alleged violations of federal law and the plaintiffs failed to show that the defendant “violated any state or federal statute”).

In Talley v. Danek Medical, Inc., 7 F.Supp.2d 725 (E.D.Va. 1998), the United States District Court for the Eastern District of Virginia noted that, in Virginia, “violation of a state or ordinance constitutes negligence per se so long as the injured person is a member of a class for whose benefit the legislation was enacted.” 7 F.Supp.2d at 731 (internal quotation marks omitted). The plaintiff in Talley v. Danek Medical, Inc. argued that the defendant illegally promoted its medical device “in violation of the federal Food, Drug, and Cosmetics Act . . . and thus, [wa]s negligent per se under Virginia law.” 7 F.Supp.2d at 731. The plaintiff’s sole support for that argument was the report of a doctor who formerly worked for the FDA. See id. at n.4. The court found that the doctor’s report was “clearly insufficient to create a genuine dispute on the question of negligence per se,” because it “consist[ed] of general and conclusory allegations regarding the practices of [the medical device] manufacturers in general.” Id. The doctor also “did not mention [the defendant] by name, specify

any conduct by [the defendant] that purportedly violated the FDCA, or provide any evidence that [the defendant] was either involved in the promotion of [the medical device] for use in . . . the spine or failed to comply with FDA promotion and labeling requirements.” Talley v. Danek Medical, Inc., 7 F.Supp.2d at 731. The court thus rejected the plaintiff’s argument, stating:

Moreover, the FDCA expressly prohibits the bringing of a private cause of action under the Act. . . . To allow a state negligence per se action based upon alleged violations of the FDCA would defeat the purpose of that prohibition. Accordingly, the Court finds that [the defendant] is entitled to summary judgment on [the plaintiff]’s FDCA-based negligence per se claim.

7 F.Supp.2d at 731.

In In re: Orthopedic Bone Screw Products Liability Litigation, 193 F.3d 781 (3d Cir. 1999), the United States Court of Appeals for the Third Circuit noted that “courts have found that violations of a federal statute or regulation constituted negligence per se under state law.” 193 F.3d at 790. The litigation in In re: Orthopedic Bone Screw Products Liability Litigation was a “multidistrict litigation compris[ing] more than 2,000 civil actions originally filed in approximately sixty of the ninety-four federal districts.” Id. at 784. The Third Circuit stated that the caselaw of other courts “make[s] clear the doctrine of per se liability does not create an independent basis of tort liability but rather establishes, by reference to a statutory scheme, the standard of care appropriate to the underlying tort.” Id. at 790. The Third Circuit stated “liability per se enables plaintiffs to establish as a matter of law that the defendant’s conduct constituted a breach of duty in a negligence action, so that only causation and damages need be proved.” Id. The Third Circuit noted that the plaintiffs’ theory in In re: Orthopedic Bone Screw Products Liability Litigation was “quite different” because they did not “invoke the statutory violations to prove defendants’ liability for a separate underlying tort, but instead contend[ed] the violations themselves form a cause of action.” Id. at 791. The Third Circuit held “[t]his interpretation of per se liability would allow private plaintiffs to recover for violations

of a federal statute that creates no private cause of action and, in fact, expressly restricts its enforcement to the federal government.” Id. The Third Circuit stated that the “[p]laintiffs’ theory would undermine section 337(a) by establishing a private state-law cause of action for violations of the FDCA, so long as those actions are brought against more than one defendant.” Id.

21 U.S.C. § 337 provides:

(a) Except as provided in subsection (b) of this section, all such proceedings for the enforcement, or to restrain violations, of this chapter shall be by and in the name of the United States. Subpoenas for witnesses who are required to attend a court of the United States, in any district, may run into any other district in any proceeding under this section.

(b)(1) A State may bring in its own name and within its jurisdiction proceedings for the civil enforcement, or to restrain violations, of section 341, 343(b), 343(c), 343(d), 343(e), 343(f), 343(g), 343(h), 343(i), 343(k), 343(q), or 343® of this title if the food that is the subject of the proceedings is located in the State.

(2) No proceeding may be commenced by a State under paragraph (1) --

(A) before 30 days after the State has given notice to the Secretary that the State intends to bring such proceeding,

(B) before 90 days after the State has given notice to the Secretary of such intent if the Secretary has, within such 30 days, commenced an informal or formal enforcement action pertaining to the food which would be the subject of such proceeding, or

(C) if the Secretary is diligently prosecuting a proceeding in court pertaining to such food, has settled such proceeding, or has settled the informal or formal enforcement action pertaining to such food.

In any court proceeding described in subparagraph (C), a State may intervene as a matter of right.

Id.

**NEW MEXICO LAW REGARDING APPLICATION OF DECISIONS
PROSPECTIVELY AND RETROACTIVELY**

Judicial decisions normally apply "retroactively, at least to the case in which the

determination was made." Castro v. United States, 540 U.S. 365, 383 (2003). The Supreme Court of New Mexico has explained that there is "a presumption that a new rule adopted by a judicial decision in a civil case will operate retroactively." Beavers v. Johnson Controls World Serv., 118 N.M. 391, 398, 881 P.2d 1376, 1383 (1994). This presumption may be overcome, however, "by an express declaration, in the case announcing the new rule, that the rule is intended to operate with modified, selective, (or even, perhaps, pure) prospectivity." Id., 118 N.M. at 398, 881 P.2d at 1383.

The Supreme Court of New Mexico explained:

Modified or selective prospectivity is the applicability of a decision to the parties in the case in which the decision is announced, whose conduct obviously occurred before announcement of the decision, but thereafter only to parties whose conduct occurs after the announcement. . . . To be contrasted with selective prospectivity are both "pure" prospectivity and retroactivity. Pure prospectivity obtains when a court applies its new rule only to conduct occurring after the rule's announcement, so that the rule does not even apply to the litigants before the court announcing the decision. Pure prospectivity is rare; a notable example in New Mexico is Hicks v. State, 88 N.M. 588, 544 P.2d 1153 (1975), order and opinion on rehearing, 88 N.M. 593, 544 P.2d 1158 (1976)(abolishing sovereign immunity but only with respect to cases arising in future). Retroactivity, on the other hand, occurs when a decision applies not only to acts occurring after announcement of the decision and to the litigants before the court, but also to acts occurring before the announcement.

Id. 118 N.M. at 397 n.7, 881 P.2d at 1383 n.7 (internal citation omitted). In Beavers v. Johnson Controls World Services, the Supreme Court set forth "retroactivity guidelines" for courts to consider in determining whether a decision should apply retroactively or prospectively:

First, the decision to be applied nonretroactively must establish a new principle of law, either by overruling clear past precedent on which litigants may have relied, or by deciding an issue of first impression whose resolution was not clearly foreshadowed.

Second, it has been stressed that we must . . . weigh the merits and demerits in each case by looking to the prior history of the rule in question, its purpose and effect, and whether retrospective operation will further or retard its operation.

Finally, we have weighed the inequity imposed by retroactive application, for where a decision of this Court could produce substantial inequitable results if applied

retroactively, there is ample basis in our cases for avoiding the injustice or hardship by a holding of nonretroactivity.

Id. 118 N.M. at 398, 881 P.2d at 1384 (internal quotation marks and bracket omitted).

In Beavers v. Johnson Controls World Services, the Supreme Court considered whether its previous decision announcing a cause of action for prima-facie tort, see Schmitz v. Smentowski, 109 N.M. 836, 785 P.2d 726 (1990), should be applied retroactively to conduct occurring before it decided Schmitz v. Smentowski. The Supreme Court concluded that the analysis of the factors was insufficient "to rebut the presumption of retroactivity attached to a judicially announced rule." Beavers v. Johnson Controls World Servs., 118 N.M. at 398, 881 P.2d at 1383.

The Supreme Court of New Mexico in Beavers v. Johnson Controls World Services concluded that the first factor, deciding that Schmitz v. Smentowski established "a new principle of law whose adoption was not clearly foreshadowed by previous decisions in [New Mexico] or other jurisdictions" was correct, but stated that its analysis did not end there. Id., 118 N.M. at 398-99, 881 P.3d at 1383-84. The Supreme Court explained that "[t]here remain[ed] for consideration the subfactor of reliance -- a factor so important in retroactivity analysis that [it thought] it deserve[d] recognition almost independent from the recognition given to the element of 'newness' in the first factor." Id., 118 N.M. at 399, 881 P.3d at 1384. The Supreme Court stated: "The extent to which the parties in a lawsuit, or others, may have relied on the state of the law before a law-changing decision has been issued can hardly be overemphasized. It is a factor that receives repeated recognition in cases discussing retroactivity vs. prospectivity." Id., 118 N.M. at 399, 881 P.3d at 1384. "In the tort context, however, a party's reliance interest is seldom as strong as it is in the commercial context." Id., 118 N.M. at 399, 881 P.3d at 1384. The Supreme Court noted that the prima-facie-tort doctrine had only been adopted by two jurisdictions at the time it adopted it, but stated, in the context of

discussing the second retroactivity factor:

Before leaving the second factor, we pause to take note of a theme that appears to underlie some of the Court of Appeals' approach to, and much of Defendants' and the Amicus Defense Lawyers Association's arguments on, the issue in this case. As already noted, Defendants and the Court of Appeals stress the point that prima facie tort has been adopted by "only two" jurisdictions. The Defense Lawyers Association elaborates on this point, saying "[e]ven those few jurisdictions that had recognized this tort did so reluctantly" and "[t]he prima facie tort concept is inconsistent with the general common law and is directly contrary to New Mexico precedent." It is probably not unfair, then, to surmise that Defendants' and Amicus's -- and perhaps also the Court of Appeals' -- view of the retroactivity issue in this case is colored by a generally hostile attitude toward the prima facie tort doctrine. And it may turn out that further experience with the doctrine will lead us to the same conclusion as was expressed, in dictum, a few years ago by an appellate court in one of the two jurisdictions that have adopted prima facie tort: "[W]e are profoundly dissatisfied with the concept of 'prima facie tort' because we regard it as unworkable[.]" Bandag of Springfield, Inc. v. Bandag, Inc., 662 S.W.2d 546, 556 (Mo.Ct.App.1983).

But uneasiness or even dissatisfaction with a rule of law is not a reason for holding that the rule shall apply only prospectively. We must take the rule as we find it, articulated and justified in a thoroughly reasoned opinion of this state's highest court, and determine whether the rule should apply to conduct predating announcement of the rule, based on the analysis reviewed here and not on one's pleasure or displeasure over the rule itself.

Beavers v. Johnson Controls World Servs., 118 N.M. at 402, 881 P.2d at 1386. Lastly, the Supreme

Court explained that the third factor

embraces, or should embrace, not only the inequity imposed on a litigant in the lawsuit in which the retroactivity question is considered, but also the potential unfairness to other claimants who have been victimized by conduct occurring before the law-changing decision but who for one reason or another have not asserted their claims until after announcement of the new rule. This, of course, is the same consideration that has prompted us to adopt the presumption of retroactivity referred to throughout this opinion: the desirability of treating similarly situated parties alike.

Id., 118 N.M. at 402, 881 P.2d at 1387. See King v. Allstate Ins. Co., 2007-NMCA-044, ¶ 21, 159

P.3d 261, 265 (stating that a judicial decision did not "represent a new concept of law, but rather employ[ed] established precepts tying liability to the obligation to pay going back more than half a century . . . established . . . when the [Supreme] Court announced that the liability of an insurance

company to pay becomes final when tort liability is found.").

NEW MEXICO LAW REGARDING BREACH OF WARRANTIES

Under the Uniform Commercial Code ("UCC"), there are at least two warranties that the manufacturer makes: (i) the implied warranty of fitness for a particular purpose; and (ii) the implied warranty of merchantability. In Perfetti v. McGhan Medical, the Court of Appeals of New Mexico, in considering the claim of an express warranty, stated: "Any express warranty made with respect to the surgeon would inure to plaintiff's benefit on the basis that the surgeon was acting as plaintiff's agent in the use of the prosthesis." 99 N.M. at 651, 662 P.2d at 652. The Court of Appeals found that there was no evidence of an express warranty that was breached. See Perfetti v. McGhan Medical, 99 N.M. at 652, 662 P.2d at 653. In discussing the claim of an implied warranty, the Court of Appeals explained that the defendant was "incorrect in urging a congruence between products liability and the implied warranty of fitness for a particular purpose. Products liability requires a defect . . . the implied warranty of fitness for a particular purpose does not require a defect." Perfetti v. McGhan Medical, 99 N.M. at 652, 662 P.2d at 653.

1. Breach of Implied Warranty.

Under the Uniform Commercial Code ("UCC"), it is the sale of goods that brings the implied-warranty provisions into operation. See Ortiz v. Gas Co., 97 N.M. 81, 84, 636 P.2d 900, 903 (Ct. App. 1981). A "sale" is defined as "the passing of title from the seller to the buyer for a price." N.M.S.A. 1978, § 55-2-106(1). To succeed on a breach of the implied warranty of fitness for a particular purpose, the plaintiff must prove: (i) a sale; (ii) that the seller had knowledge of the particular use for which a good was purchased; (iii) that the buyer relied on the seller's skill or judgment regarding the selection of goods; and (iv) that the buyer purchased a product with a particular purpose for that product in mind. See Spectron Dev. Lab. v. Am. Hollow Boring Co.,

1997-NMCA-025, ¶ 40, 936 P.2d 852, 861 (citing N.M.S.A. 1978, § 55-2-314); Daniell v. Ford Motor Co., Inc., 581 F.Supp 728, 731 (D.N.M. 1984)(citing N.M.S.A. 1978, § 55-2-314(2)(c)). N.M.S.A. 1978, § 55-2-315 provides:

Where the seller at the time of contracting has reason to know any particular purpose for which the goods are required and that the buyer is relying on the seller's skill or judgment to select or furnish suitable goods, there is unless excluded or modified under the next section an implied warranty that the goods shall be fit for such purpose.

Id.

2. Breach of Warranty of Merchantability.

To establish a claim for breach of the implied warranty of merchantability, a plaintiff must prove that the seller sold goods or products that failed to meet the statutory definition of “merchantable.” N.M.S.A. 1978, § 55-2-314; N.M.R.A. 2008, Civ. UJI 13-1430. N.M.S.A. 1978, § 55-2-314 defines “merchantable”:

(1) Unless excluded or modified (Section 2-316), a warranty that the goods shall be merchantable is implied in a contract for their sale if the seller is a merchant with respect to goods of that kind. Under this section the serving for value of food or drink to be consumed either on the premises or elsewhere is a sale.

(2) Goods to be merchantable must be at least such as:

- (a) pass without objection in the trade under the contract description; and
- (b) in the case of fungible goods, are of fair average quality within the description; and
- (c) are fit for the ordinary purposes for which such goods are used; and
- (d) run, within the variations permitted by the agreement, of even kind, quality and quantity within each unit and among all units involved; and
- (e) are adequately contained, packaged and labeled as the agreement may require; and

(f) conform to the promises or affirmations of fact made on the container or label if any.

(3) Unless excluded or modified (Section 2-316) other implied warranties may arise from course of dealing or usage of trade.

Id. A supplier breaches this warranty if the product is defective and is not fit for the ordinary purposes for which such product is used. See Pac. Indem. Co. v. Therm-O-Disc, Inc., 476 F. Supp. 2d 1216, 1225 (D.N.M. 2006)(“A manufacturer must use ordinary care in the designing, making, inspecting, and packaging of the product. UJI 13-1410 NMRA 2006. Ordinary care is that care which a reasonably prudent supplier would use in the conduct of its business.”)(citing N.M.R.A. 2006, UJI 13-1404).

A breach of implied warranty of merchantability claim requires proof of a defect. See Pac. Indem. Co. v. Therm-O-Disc, Inc., 476 F. Supp. 2d at 1223. New Mexico Uniform Civil Jury Instruction No. 13-1430 provides:

A supplier breaches the implied warranty of merchantability:

[1. If the goods sold would be rejected by someone knowledgeable in the trade for failure to meet the contract description]; [or]

[2. If goods sold in bulk are not of fair average quality for the type of goods described by the contract. The goods need not be the best quality but they must pass without objection in the trade]; [or]

[3. If the [goods] [products] are defective and are not fit for the ordinary purposes for which such [goods] [products] are used]; [or]

[4. If the goods do not run within variations permitted by the contract for the reason that there are wide differences in type, quality and quantity within delivered units and among all units involved]; [or]

[5. If the [goods] [products] are not adequately contained, packaged and labeled as required by the contract]; [or]

[6. If the [goods] [products] do not conform to the promises or statements made by

the seller on the container or label]; [or]

[7. If the food or drink is unwholesome or unfit for human consumption].

N.M.R.A. 2008, Civ. UJI 13-1430. The directions for use of this instruction state: “Select the bracketed material which fits the actual issues and evidence involved in the case. With this instruction, UJI 13-1429 must also be used. This list of items is not exclusive. Reference should be made to the Uniform Commercial Code 55-2-314 NMSA 1978 for further specifications.”

NEW MEXICO LAW REGARDING PUNITIVE DAMAGES

“Punitive damages do not measure a loss to the plaintiff, but rather punish the tortfeasor for wrongdoing and serve as a deterrent.” Sanchez v. Clayton, 117 N.M. 761, 766, 877 P.2d 567, 572 (1994). To be liable for punitive damages, a wrongdoer must have some culpable mental state and the wrongdoer's conduct must rise to a willful, wanton, malicious, reckless, oppressive, or fraudulent level. See Clay v. Ferrellgas, Inc., 118 N.M. 266, 269, 881 P.2d 11, 14 (1994). “Punitive damages are only appropriate to punish conduct that is overreaching, malicious, or wanton conduct . . . is inconsistent with legitimate business interests, that violates community standards of decency, and tends to undermine the stability of expectations essential to contractual relationships.” N.M. Banquest Investors Corp. v. Peters Corp., 2007-NMCA-065, ¶ 28, 159 P.3d 1117, 1127 (internal quotation marks and bracket omitted).

“Whether conduct arises to the level such that punitive damages are appropriate is a mixed issue of fact and law.” Id. ¶ 29, 159 P.3d at 1127. “A mental state sufficient to support an award of punitive damages will exist when the defendant acts with reckless disregard for the rights of the plaintiff -- i.e., when the defendant knows of potential harm to the interests of the plaintiff but nonetheless utterly fails to exercise care to avoid the harm.” McNeill v. Rice Eng'g and Operating, Inc., 2003-NMCA-078, ¶ 32, 70 P.3d 794 (internal quotation marks and bracket omitted).

“Recklessness in the context of punitive damages is the intentional doing of an act with utter indifference to the consequences.” Couch v. Astec Indus., Inc., 2002-NMCA-084, ¶ 58, 53 P.3d 398, 411 (internal quotation marks omitted). See Faniola v. Mazda Motor Corp., No. CIV-02-1011, 2004 WL 1354469 *1 (D.N.M. April 30, 2004)(Browning, J.)(“Because [plaintiff] has not established a genuine issue of material fact whether she is entitled to an award of punitive damages, the Court will grant the Defendants’ motion and enter summary judgment dismissing [plaintiff’s] seventh cause of action for punitive damages.”).

“In a product liability case, the knowledge factor is extremely important. A defendant that is unaware of a product's defect can hardly ‘consciously’ or ‘recklessly’ disregard any other party's rights. Numerous cases bear out the proposition that with every award of punitive damages, the defendant-manufacturer was aware of the existing defect and also aware of the serious danger of substantial harm posed by that defect.” Id. at *6 (internal quotation marks and bracket omitted).

LAW REGARDING DIRECT-TO-CONSUMER ADVERTISING

In a 2007 article regarding direct-to-consumer advertising of prescription drugs, the authors opine that “[e]vidence suggests that direct-to-consumer advertising of prescription drugs increases pharmaceutical sales and both helps to avert underuse of medicines and leads to potential overuse.” Response, Exhibit 11, J. Donohue, M. Cevalco, and M. Rosenthal, A Decade of Direct-to Consumer Advertising of Prescription Drugs, 357:7 N. Engl. J. Med. 673 (2007)(“Donohue article”). The authors noted that “[t]otal spending on pharmaceutical promotion grew from \$11.4 billion in 1996 to \$29.9 billion in 2005.”). Donohue article at 11.

In 1999, the Supreme Court of New Jersey held that, to the extent that a drug manufacturer engages in direct-to-consumer advertising, it has a concomitant duty to warn consumers directly. See Perez v. Wyeth Lab. Inc., 734 A.2d 1245, 1256-57 (N.J. 1999)(stating that “[c]onsumer-directed

advertising of pharmaceuticals thus belies each of the premises on which the learned intermediary doctrine rests” and thus concluding “that the learned intermediary doctrine does not apply to the direct marketing of drugs to consumer.”). The Supreme Court of New Jersey is the only court that has recognized a mass-marketing or direct-to-consumer (“DTC”) advertising exception to the learned-intermediary doctrine. See, e.g., Beale v. Biomet, Inc., 492 F. Supp. 2d 1360, 1376 (S.D. Fla. 2007)(“Since Perez was decided, no court -- including any Florida court -- has recognized the DTC exception to the learned intermediary doctrine, and several courts have expressly rejected the DTC exception.”); Colacicco v. Apotex, Inc., 432 F. Supp. 2d 514, 547 n.30 (E.D. Pa. 2006)(“If we reached the merits of the LID issue, any direct-to-consumer (“DTC”) advertising exception would likely not apply. This is because, in the eight years since Perez, the New Jersey Supreme Court case making an exception to the LID for direct-to-consumer advertising, was decided, no state has joined New Jersey.”). As the United States District Court stated in Cowley v. Abbott Labs., Inc., 476 F. Supp. 2d 1053 (W.D. Wis. 2007):

Plaintiffs argue defendant Abbott lost its protection under the Learned Intermediary Doctrine because it engages in direct-to-consumer advertising. Plaintiffs cite Perez v. Wyeth Laboratories, Inc., 161 N.J. 1, 734 A.2d 1245 (1999) in support of their argument. However, there is no evidence that North Carolina has adopted such an exception to the Learned Intermediary Doctrine.

476 F.Supp.2d at 1060 n.4.

ANALYSIS

Mark Rimbart contends that “[t]hree of Lilly’s bases for seeking summary judgment are affirmative defenses, i.e., (1) the learned intermediary doctrine, (2) the comment k to § 402A of the Restatement (Second) of Torts immunity for ‘unavoidably unsafe’ products, and (3) the claim that a voluntary suicide by a person of ‘sound mind’ is an intervening cause.” Response at 7. Mark Rimbart contends that this posture is significant in a summary judgment context, because Eli Lilly

can obtain summary judgment on an affirmative defense, as to which it bears the proof, only if it makes the showing that is “sufficient for the court to hold no reasonable trier of fact could find other than for the moving party.” Paul v. Monts, 906 F.2d at 1474 (stating that “where the moving party has the burden -- the plaintiff on a claim for relief or the defendant on an affirmative defense -- his showing must be sufficient for the court to hold that no reasonable trier of fact could find other than for the moving party.”)(internal quotations omitted). Eli Lilly has not met that burden on most of its motion.

I. THE COURT WILL NOT GRANT ELI LILLY SUMMARY JUDGMENT ON MARK RIMBERT’S FAILURE-TO-WARN CLAIMS.

While Mark Rimbert urges the Court to certify the issue of whether the Supreme Court of New Mexico would adopt the learned-intermediary doctrine, the Court does not believe that the issue meets the requirements for certification under state law. There are controlling New Mexico Court of Appeals cases. Accordingly, the Court will decline to certify the case to the Supreme Court, but will also decline to follow the Court of Appeals cases.

A. THE COURT WILL NOT CERTIFY THE LEGAL QUESTION PRESENTED TO THE SUPREME COURT OF NEW MEXICO.

Mark Rimbert asks the Court to either: (i) make an Erie prediction that the Supreme Court of New Mexico will reject the learned-intermediary doctrine outright; or (ii) certify the question to the Supreme Court of New Mexico in accordance with N.M.R.A., Rule 12-607. See Response at 1.

It is thus appropriate for the Court to first determine whether the Court should certify the legal question to the Supreme Court of New Mexico. See Response at 11. Mark Rimbert also suggests “phraseology for the question.” Id. That suggested question is: “Does New Mexico adopt the ‘learned intermediary’ doctrine as articulated in the Restatement (Third) of Torts, Product Liability, § 6(d)(1), and if so, does New Mexico also recognize the limitations or qualifications on that

doctrine, as expressed in Restatement (Third) of Torts, Product Liability § 6(d)(2)?” Response at 11 n.9.

Under N.M.R.A., Rule 12-607(A)(1), the Supreme Court of New Mexico “may answer by formal written opinion questions of law certified to it by a court of the United States . . . if the answer may be determinative of an issue in pending litigation in the certifying court and the question is one for which answer is not provided by a controlling: (a) appellate opinion of the New Mexico Supreme Court or the New Mexico Court of Appeals.” N.M.R.A. Rule 12-607(A)(1). The Court does not believe that it is appropriate to certify Mark Rimbart’s proposed questions to the Supreme Court of New Mexico, given the three Court of Appeals of New Mexico cases regarding the issue of learned-intermediary. See Serna v. Roche Labs, 101 N.M. 522, 684 P.2d 1187 (Ct. App. 1984), Perfetti v. McGhan Med., 99 N.M. 645, 662 P.2d 646 (Ct. App.1983); Hines v. St. Joseph’s Hosp., 86 N.M. 763, 527 P.2d 1075 (Ct. App. 1974). While the federal court would like to have the answer of the Supreme Court of New Mexico, the Supreme Court of New Mexico did not draft its certification rule precisely with the federal court’s Erie duty in mind, and this Court’s task in this case and the rule’s intent are somewhat different.

The Court’s task is to divine, as much as possible, what the Supreme Court of New Mexico would do if the legal question was presented to it. Rule 12-607(A)(1), on the other hand, is worded to provide other courts an interpretation of New Mexico law when there is no controlling appellate case from New Mexico. A lack of appellate decisions from New Mexico is not the situation here. The problem is that there is no controlling Supreme Court of New Mexico decision.

The Court could nonetheless certify the question to the Supreme Court of New Mexico and see if the Supreme Court ignored the language of its rule and took the certification. Such a route is probably tantalizing to Mark Rimbart, who fears that he may win this motion, win at trial, have the

Tenth Circuit certify the legal question, and then, after so much time and effort invested in the case, have the Supreme Court of New Mexico state that the Court was wrong in its state-law interpretation. Nevertheless, the Court does not think that is an appropriate way for the Court to deal with the Supreme Court of New Mexico. The Court should not act on the assumption that the Supreme Court will ignore the language of its rules.

Here, there are three New Mexico Court of Appeals decisions adopting the learned-intermediary doctrine. The Court's task is to consider those opinions carefully and determine whether there is a good indication of how the Supreme Court of New Mexico would rule if the question was presented to it. Accordingly, the Court will decline Mark Rimbert's request that the Court certify the legal issue to the Supreme Court of New Mexico and will proceed to determine the issue of state law.

B. THE COURT DOES NOT BELIEVE THAT THE SUPREME COURT OF NEW MEXICO WOULD ADOPT THE LEARNED-INTERMEDIARY DOCTRINE.

Eli Lilly contends that New Mexico has adopted the learned-intermediary doctrine. The Supreme Court of New Mexico has yet, however, to expressly adopt the learned-intermediary doctrine. In State ex rel. Johnson and Johnson Corp. v. Karl, the Supreme Court of Appeals of West Virginia explained: "The court stated that "the highest courts of . . . twenty-two states, . . . [including] New Mexico . . . have not adopted the learned intermediary doctrine." 647 S.E.2d at 905. The New Mexico cases upon which Eli Lilly relies on do not expressly use the term "learned-intermediary." Further, Serna v. Roche Labs, Perfetti v. McGhan Med., and Hines v. St. Joseph's Hosp. are cases that date from the 1970s and 1980s.

In the three available New Mexico appellate cases, while the Court of Appeals did not use the term "learned-intermediary," it held that "the manufacturer's duty to warn is fulfilled if it warns the

physician, not the patient.” Serna v. Roche Labs, 101 N.M. at 524, 684 P.2d at 1189. The Court believes that, fairly read, the Court of Appeals of New Mexico has adopted the learned-intermediary doctrine and at the hearing Mark Rimbert’s counsel conceded that readily. See Tr. at 37:16-18 (stating that the cases “certainly talk about warning the . . . physician but they don't even use the name of this quote widely accepted doctrine.”). The Court believes that the Supreme Court of New Mexico would not, in 2008, adopt the doctrine of learned-intermediary and would decline to follow the Court of Appeals cases from the 1970s and 1980s.

The primary reason that the Court believes that the Supreme Court of New Mexico would not adopt the learned-intermediary doctrine is that it is fundamentally inconsistent with New Mexico’s strict-liability jurisprudence. First, New Mexico has adopted strict liability on product manufacturers to ensure that the risk of loss for injury resulting from defective products is borne by the suppliers, principally because they are in a position to absorb the loss by distributing it as a cost of doing business. The learned-intermediary doctrine shifts the risk to the physician and to the patient. If the Supreme Court of New Mexico adopts the learned-intermediary doctrine, the risk of loss will not be able to be spread, but will largely be borne by the physician and/or the patient. The Court does not believe that the Supreme Court of New Mexico would weaken this pillar of the strict-liability doctrine.

Second, New Mexico also adopted the strict liability doctrine to promote fairness by ensuring that the plaintiffs injured by an unreasonably dangerous product are compensated for their injuries. The learned-intermediary doctrine would leave some plaintiffs uncompensated. The Court does not believe that the Supreme Court of New Mexico would choose a doctrine that would leave plaintiffs uncompensated when there does not appear to be a compelling reason for them to be uncompensated. The Supreme Court of New Mexico explained in Brooks v. Beech Aircraft Corp., that:

The policy of risk- or cost-distribution continues to serve as a primary basis for imposing strict products liability. . . . In addition to the cost-distribution rationale . . . other courts have approved specifically the rationale that imposing strict liability relieves plaintiffs of the burden of proving ordinary negligence under circumstances in which such negligence is likely to be present but difficult to prove. . . . The third policy cited for the imposition of strict liability is that suppliers who otherwise might not be liable because of a passive role in the chain of supply should be encouraged to select reputable and responsible manufacturers who generally design and construct safe products and who generally accept financial responsibility for injuries caused by their defective products. . . . Fourth and finally, imposing strict products liability serves the interests of fairness.

120 N.M. at 375-76, 902 P.2d at 57-58 (internal citations omitted). In Stang v. Hertz Corp., 83 N.M. 730, 497 P.2d 732 (1972), the Supreme Court of New Mexico adopted the strict liability doctrine, stating:

The history of the evolution of strict products liability, its policy basis and prerequisites to recovery does reveal a recognition by the courts of traditional common law concepts of status and responsibility. It was referred to by Professor Keeton as ‘impressive evidence of continuing reform of tort law through candidly creative judicial action. . . . One of the great virtues of the common law is its dynamic nature that makes it adaptable to the requirements of society at the time of its application in court. . . . We feel that the conditions and the needs of the times makes it appropriate for such changes as we are here making. Most of the states who have adopted strict liability have done so through the judicial system. This has been called following the leader and we see nothing wrong with this general principle if the leader is going in the right direction.

83 N.M. at 735, 497 P.2d at 737. Mark Rimbart argued at the May 16, 2008 hearing that the “policy rationales that [the Supreme Court of New Mexico] found persuasive in ‘72 [for adopting strict liability] are equally as persuasive in adopting the [State ex rel. Johnson and Johnson Corp. v. [Karl]], the Supreme Court of West Virginia’s] rejection of learned intermediary.” Tr. at 51:13-15 (Vickery). Eli Lilly counters that the learned-intermediary doctrine “derive[s] from § 402A of the Restatement (Second) of Torts.” Post-Hearing Memo. at 7 (underlining added). The Tenth Circuit stated in Thom v. Bristol-Myers Squibb Co. that “[t]he learned intermediary doctrine derives from §402A of the Restatement (Second) of Torts.” 353 F.3d at 851 (citing Edwards v. Basel Pharmaceuticals, 933 P.2d

298, 300 (Okla. 1997))(underlining added).³ The Tenth Circuit also noted that Wyoming had adopted the Restatement (Second) of Torts in its entirety. See Thom v. Bristol-Myers Squibb Co., 353 F.3d at 852. The Tenth Circuit noted in Thom v. Bristol-Myers Squibb Co. that § 402A provides “that a seller of a defective, unreasonably dangerous product is strictly liable for physical harm to a consumer” and that “[c]omment k . . . establishes that this rule does not apply to ‘unavoidably unsafe products.’” 353 F.3d at 852. Although the Tenth Circuit was convinced in Thom v. Bristol-Myers Squibb Co. that Wyoming would adopt the learned-intermediary doctrine, the Court is not convinced that the Supreme Court of New Mexico would adopt the doctrine. Unlike its prediction of Wyoming law in Thom v. Bristol-Myers Squibb Co., the Tenth Circuit has not implied that New Mexico would adopt the learned-intermediary doctrine. Moreover, the Supreme Court of New Mexico explained in Brooks v. Beech Aircraft Corp.:

The policy of risk- or cost-distribution continues to serve as a primary basis for imposing strict products liability. . . . In addition to the cost-distribution rationale . . . other courts have approved specifically the rationale that imposing strict liability relieves plaintiffs of the burden of proving ordinary negligence under circumstances in which such negligence is likely to be present but difficult to prove. . . . The third policy cited for the imposition of strict liability is that suppliers who otherwise might not be liable because of a passive role in the chain of supply should be encouraged to select reputable and responsible manufacturers who generally design and construct safe products and who generally accept financial responsibility for injuries caused by their defective products. . . . Fourth and finally, imposing strict products liability serves the interests of fairness. At the heart of this judgment lies the conclusion that although the manufacturer has provided a valuable service by supplying the public with a product that it wants or needs, it is more fair that the cost of an unreasonable risk of harm lie with the product and its possibly innocent manufacturer than it is to visit the entire loss upon the often unsuspecting consumer who has relied upon the expertise of the manufacturer when selecting the injury-producing product.

³ Eli Lilly also cites Ehlis v. Shire Richwood, Inc. 367 F.3d 1013, 1017 (8th Cir. 2004)(“North Dakota has adopted section 402A of the Restatement (Second) of Torts, from which the learned intermediary evolves.”)(underlining added); Eck v. Park, Davis & Co., 256 F.3d 1013, 1017 (10th Cir. 2001)(explaining that the Supreme Court of Oklahoma relied upon comment k to § 402A of the Restatement (Second) of Torts in adopting the learned intermediary doctrine).

120 N.M. at 375-76, 902 P.2d at 57-58 (internal citations omitted). When Wyoming adopted §402A of the Restatement (Second) of Torts, it explained:

When a defective article enters the stream of commerce and an innocent person is hurt, it is better that the loss fall on the manufacturer, distributor or seller than on the innocent victim. This is true even if the entities in the chain of production and distribution exercise due care in the defective product's manufacture and delivery. They are simply in the best position to either insure against the loss or spread the loss among all the consumers of the product.

Ogle v. Caterpillar Tractor Co., 716 P.2d at 342. In addition, the Supreme Court of Wyoming explained “the cause of action for strict liability in tort is necessary because of the inadequacies of breach of warranty actions when applied to claims in tort for personal injury.” Id. at 344. While the Supreme Court of Wyoming’s rationale for adopting strict liability is, in some respects, similar to the Supreme Court of New Mexico’s rationale, the Supreme Court of New Mexico also expressed a specific

judgment . . . that although the manufacturer has provided a valuable service by supplying the public with a product that it wants or needs, it is more fair that the cost of an unreasonable risk of harm lie with the product and its possibly innocent manufacturer than it is to visit the entire loss upon the often unsuspecting consumer who has relied upon the expertise of the manufacturer when selecting the injury-producing product.

Brooks v. Beech Aircraft Corp., 120 N.M. at 376, 902 P.2d at 59. Allowing drug manufacturers to shift the burden of defective product to physicians would undermine the Supreme Court of New Mexico’s conclusion that the burden should be on the manufacturer, upon whose “expertise” an “often unsuspected consumer” has relied in “selecting the injury-producing product.” Because the learned-intermediary doctrine is contrary to the policies articulated by the Supreme Court of New Mexico for its adoption of strict liability in the products-manufacturing area, the Court is not persuaded that the Supreme Court of New Mexico would create this exception to its strong strict-liability jurisprudence. Moreover, while Eli Lilly contends that “[c]onsideration of the general

weight and trend of authority concerning the learned intermediary doctrine also supports an Erie prediction that New Mexico courts would continue to recognize and apply it” and that “courts in forty-eight states, as well as Puerto Rico and the District of Columbia, recognize and apply the doctrine,” Post-Hearing Memo. at 5, the Court does not believe that the trend is clear.

The Court believes that the Supreme Court of New Mexico would be more persuaded by the analysis in State ex rel. Johnson and Johnson Corp. v. Karl rather than what other courts, including many state courts and the New Mexico Court of Appeals, have found. The Supreme Court of Appeals of West Virginia noted that:

Among the primary justifications that have been advanced for the learned intermediary doctrine are (1) the difficulty manufacturers would encounter in attempting to provide warnings to the ultimate users of prescription drugs; (2) patients' reliance on their treating physicians' judgment in selecting appropriate prescription drugs; (3) the fact that it is physicians who exercise their professional judgment in selecting appropriate drugs; (4) the belief that physicians are in the best position to provide appropriate warnings to their patients; and (5) the concern that direct warnings to ultimate users would interfere with doctor/patient relationships.

Id. The Supreme Court of West Virginia stated it found “these justifications for the learned intermediary doctrine to be largely outdated and unpersuasive.” Id. at 906. The Court believes that the Supreme Court of New Mexico would make a similar finding.

As noted by Mark J. Penn and E. Kinney Zalesne in Microtrends, The Small Forces Behind Tomorrow's Big Changes (Twelve 2007)(hereinafter “Microtrends”),

the biggest trend in American health care is DIYD -- Do-It-Yourself-Doctors. These are people who research their own symptoms, diagnose their own illnesses, and administer their won cures. If they have to call on doctors at all, they either treat them like ATM machines for prescriptions they already “know” they need, or they show up in their offices with full-color descriptions of their conditions, self-diagnosed on WebMD.

Id. at 91. Penn and Zalesne contend that “DIYDs are having a big impact. Drug companies have seen the power of direct-to-consumer (DTC) ads, like the ones that swamp TV nightly for Viagra,

Cialis, and ‘Ask Your Doctor if the Purple Pill is Right for You.’” Id. at 94. The prescription drug manufacturers have spent billions of dollars on DTC advertising, and the trend is towards further spending on DTC advertising. See Mictrotrends at 94 (noting that, “[w]hile [the drug companies] spend the bulk of their marketing dollars on doctors, the growth in DTC ads has been dramatic: in 1997, drug companies spent about \$1 billion on DTC ads; by 2004, it was over \$4 billion.”). Penn and Zalesne ask:

Is DIYD a good trend? Since people can’t sue themselves for malpractice we may never know. Of course, we may see more lawsuits against drug companies for insufficient disclosure of information, which is even more critical in self-treatment. (Although, really, how much longer or more detailed could those drug warning labels be?).

Id. at 95. The Court believes this two-pronged phenomena -- a dramatically increased marketing directed to consumers and the use of the interest by consumers to conduct their own medical research -- would persuade the Supreme Court of New Mexico that the justification for the learned-intermediary doctrine is quickly becoming, if not already the case, outdated.

The Court believes that the Supreme Court of New Mexico would find that the changed landscape makes the justifications other courts have used for the learned-intermediary doctrine outdated and unpersuasive. With the advent of DTC advertising and the trend of people self-diagnosing and, based on that diagnosis, requesting particular prescription drugs, the reliance on physicians is not the same as it was in the 1970s and 1980s. While the Court does not in any way minimize the importance of doctors in the prescription-drug claim, neither the drug manufacturers nor the patient totally relies on the intermediary. The manufacturer and the patient are communicating directly and the consumer is relying on that direct communication.

First, the Court is not convinced that the difficulty manufacturers would encounter in attempting to provide warnings to the ultimate users of prescription drugs counsels that the Supreme

Court of New Mexico would adopt the learned-intermediary doctrine. While the Court does not minimize the difficulty of drafting adequate warnings, the Court is not convinced that the task of drafting adequate warnings for doctors is so measurably different from drafting sufficient warnings for consumer that the Court should not require warnings for consumer. The drug manufacturer still has to prepare warnings. It can give a set to the doctors, one in the package, and put one on the internet. As the Supreme Court of New Jersey recognized in Perez v. Wyeth Laboratories, Inc.:⁴

Pharmaceutical companies have a right to communicate with the public. These companies hope to increase their market share by making their product well known to both patients and physicians. Pharmaceutical executives, aware of the high levels of spending on DTC efforts, are trying to determine how to best spend their funds to obtain the highest return on their investment. Since the FDA Guidance was released, pharmaceutical companies have taken consumer advertising crash courses. Pharmaceutical companies are already seeing results in strong sales growth, due to DTC advertising. . . . The direct marketing of drugs to consumers generates a corresponding duty requiring manufacturers to warn of defects in the product.

734 A.2d at 1263. While the warnings to the doctor and the consumer may not be exactly the same, the differences do not appear to justify not giving the consumer any warning.

Second, the Court is not convinced the patients' reliance on their treating physicians' judgment in selecting appropriate prescription drugs counsels that the Supreme Court of New Mexico would adopt the learned-intermediary doctrine. There is nothing inconsistent with a patient relying on his or her doctor, and reading warning labels. The informed consumer is likely to ask the

⁴ The Court notes that other courts have rejected New Jersey's exception to the learned-intermediary doctrine. See Beale v. Biomet, Inc., 492 F.Supp.2d 1360, 1376 (S.D. Fla 2007); Colacicco v. Apotext, Inc., 432 F.Supp.2d 514, 547 n.30 (E.D. pa. 2006), aff'd on other grounds, 521 F.3d 523 (3d Cir. 2008); Cowley v. Abbott Labs, Inc., 476 F.Supp.2d 1053, 1060 n.4 (W.D. Wis. 2004); In re Meridia Prods. Liab. Litig., 328 F.Supp.2d 791, 812 n.19 (N.D. Ohio 2004); In re Norplant Contraceptives Prods. Liab. Litig., 215 F.Supp.2d at 811-12. The Court notes other courts have limited the application of New Jersey's rule. See Appleby v. Glaxo Wellcome, Inc., No. Cv-0062 (RBK), 2005 WL 3440440 at *5 (D.N.J. December 13, 2005); Heindel v. Pfizer, Inc., 381 F.Supp.2d 364, 384 (D.N.J. 2004).

physician more questions, and informed responses may increase reliance rather than decrease reliance. The warnings may make the relationship more dynamic rather than one-sided.

The Court has no reason to believe that the modern doctor does not expect or is wary of such a relationship. Doctors know more than most that prescription drugs do not act the same in each person; indeed, because each body is unique, the drug will not work exactly the same in any two people. Thus, the careful doctor relies heavily on the patient to tell the doctor how the body is reacting to the drug. The doctor often encourages the patient to cease taking the drug if certain symptoms occur. Thus, the Supreme Court of New Mexico is unlikely to find the modern patients' reliance on their treating physicians' judgment in selecting appropriate prescription drugs is inconsistent with requiring adequate warnings for the consumer as well as the doctor.

Third, there is no doubt that it is the physicians who exercise their professional judgment in selecting appropriate drugs. But refusal to adopt the learned-intermediary doctrine does not impact adversely the exercise of that professional judgment in any way. The manufacturer will still have incentive to prepare adequate warnings and completely educate physicians about their drugs. And a better informed client is likely to help, not hinder, the doctors' exercise of their professional judgment. Doctors are fully exposed to New Mexico's malpractice law for their exercise of professional judgment; there does not appear to be a sound reason to tell the pharmaceutical company it does not need to help inform the patients, who may, fully informed, be the best source of informing the physicians' exercise of their professional judgment.

Fourth, the Court questions whether physicians are in the best position to provide appropriate warnings to their patients. It would seem that the manufacturer is the best to provide the warnings. The manufacturer is the one who has the best access to the range of research and development history; the doctor does not have time to research each pharmaceutical as thoroughly as the

manufacturer. While the doctor is the one talking directly to the patient, the time that a doctor has for each patient is severely limited by both economics and the need to provide health care to more than can adequately be served. See State ex rel. Johnson and Johnson Corp. v. Karl, 647 S.E.2d at 910 (stating that “because managed care has reduced the time allotted per patient, physicians have considerably less time to inform patients of the risks and benefits of a drug.”). The physician may be able to provide the most salient highlights of the warning, but there is no sound reason to use that reality to tell the manufacturer not to provide warnings to the patient, who, with informed questions, may make the limited conversation more informative for both the doctor and the patient. In 1993, a scholar observed that

the volume and potential for overpromotion of drug information renders the physician an ineffective intermediary. Challenged by a constant bombardment of drug literature from manufacturers, the physician frequently is unable to keep up with the daily changes in the state of medical knowledge. The sheer volume of drug literature argues against the physician being informed of all the hazards of all the drugs and devices he or she prescribes. This is especially true when a drug's side effects are discovered only after the physician has received and relied upon the drug manufacturer's initial marketing literature.

S. Casey, Comment, Laying an Old Doctrine to Rest: Challenging the Wisdom of the Learned Intermediary Doctrine, 19 Wm. Mitchell L. Rev. 931, 957 (1993). In 2008, scholars Richard B. Goetz and Karen R. Growden contended that the Supreme Court of New Jersey in Perez v. Wyeth Laboratories, Inc. and the Supreme Court of West Virginia in State ex rel. Johnson and Johnson Corp. v. Karl made the “key assumption of arguments for limiting or abolishing the learned intermediary doctrine, albeit one not always clearly expressed . . . that DTC advertising not only alters the physician-patient relationship but essentially eliminates the physician's role in the choice of a prescription medicine.” R. Goetz & K. Growdon, A Defense of the Learned Intermediary Doctrine, 63 Food & Drug L.J. 421, 431 (2008). Goetz and Growden noted that “[t]he conclusion -- implicit

. . . that physicians do not independently weigh relevant risks and benefits in prescribing an advertised drug does not follow from the fact that the drug was advertised.” Id. at 432. The Court agrees that the advent of direct-to-consumer advertising does not necessarily mean that physicians no longer independently weigh risks and benefits when prescribing drugs, but does believe that physicians may not be in the best position -- and should not be in the sole position -- to provide necessary warnings about drugs to their patients. Professors Thuy D. Pham and Annette P. Martinez have observed that:

The . . . argument -- that the learned intermediary will make sure that all the right drugs reach the right patients -- is valid. However, the logic fails when one considers what has been mentioned time and again in legal literature regarding drug design: physicians do not make design choices, nor do they oversee the manufacturer in designing drug formulations. The role and focus of a private physician is healing his patient. Conceptualizing drug design does not emanate from him; instead, he chooses the appropriate drug therapy from already available drug designs in the market and then prescribes it to his patient.

Physicians do not have independent expertise regarding the details of prescription products and do not know nearly as much as manufacturers the efficacy and safety of drugs. They may rely on manufacturers' extensive advertising, promotional programs and medical sales representatives to learn about the product -- sources that do not provide a complete or accurate picture of product risks. Furthermore, physicians do not always remain up-to-date on available information -- it is not uncommon for doctors to continue to prescribe familiar forms of medication even if newer alternative drugs released out in the market are more efficacious and safe. Generally, the role of the private physician is one of passive reliance on the manufacturer as the expert.

T. Pham and A. Martinez, The Polio Vaccine and the Restatement (Third) of Torts: Why the Controversies?, 11 DePaul J. Health Care L. 125, 146 (2008). In any case, the Court is not convinced that the belief by some that physicians are in the best position to provide appropriate warnings to their patients is inconsistent with requiring the manufacturer to warn and inform the patient.

Finally, the Court does not believe that the Supreme Court of New Mexico will share some courts' concerns that direct warnings to ultimate users would interfere with doctor/patient

relationships. It is difficult to think of how more information would interfere with the relationship; if anything, the relationship will be more informed. The Court does not think this speculative fear counsels against rejection of the learned-intermediary doctrine.

One possible objection is that, even if the Court concludes that the Supreme Court of New Mexico would not adopt the learned-intermediary doctrine, this case is not the one in which to make that ruling. Gilbert Rimbart did not ask for Prozac by name. See Hochstadt Depo. at 123:17-20. There is no evidence that Gilbert Rimbart saw any type of advertisement for Prozac. See Memo. in Support, Exhibit D, Deposition of Tracy Rimbart Thiel at 36:3-9 (taken May 22, 2007)(“Thiel Depo.”). There is no evidence that Gilbert Rimbart had any Prozac prescription filled at a pharmacy. See Jackson Depo. at 97:24-99:3.

On the other hand, the Court notes that a bottle marked Prozac was on the table where Gilbert Rimbart was seated at the time of his death. See M. Rimbart Depo. at 28:23-29:5. The bottle did not have a pharmacy label, nor did it state Gilbert Rimbart’s name or other identifying information. See Y. Rimbart Depo. at 14:23-16:14. Family members found an unfilled prescription for Prozac written for Gilbert Rimbart when they cleaned the home after his death. See M. Rimbart Depo. at 15:15-17:4. The presence of fluoxetine and its psychoactive metabolite, norfluoxetine, in Gilbert Rimbart’s blood was confirmed by toxicological examination. See Toxicology Report at 1.

The Court does not believe that the facts of this case should be determinative whether the Court concludes the Supreme Court of New Mexico will adopt the learned-intermediary doctrine. It is more relevant what factors the Supreme Court will encounter in some future case before it, and the Court would be speculating what the Supreme Court might encounter. The Supreme Court might encounter a case where the plaintiff had thoughtfully read the warnings and they were inadequate. In any case, the rule developed should not depend so heavily on the facts of the case before it, but

should be one that is appropriate for a broad range of cases, and in fact, for society as whole, not just the individuals who decide to litigate.

The Court is not prepared to say that the Supreme Court of New Mexico would adopt the learned-intermediary doctrine under the circumstances of this case or as a matter of state law.⁵ The Court also finds that there is no clear indication that the Supreme Court of New Mexico would create an exception to its strict-liability law, would adopt the learned-intermediary doctrine, or follow the state Court of Appeals cases from the 1970s and 1980s. The Court believes that the Supreme Court of New Mexico, given the opportunity in 2008, would not adopt the learned-intermediary doctrine, because of the erosion of the justifications for adoption of the doctrine, given the changing dynamics between doctors and patients, patients' self-diagnosis, and DTC advertising by drug manufacturers.

The Court of Appeals of New Mexico noted in Richards v. Upjohn Co.: "Although some

⁵ The Court notes that Eli Lilly argues other jurisdictions have cited Perfetti v. McGhan Med., 99 N.M. 645, 662 P.2d 646, 651 (Ct. App. 1983), and Hines v. St. Joseph's Hosp., 86 N.M. 763, 764, 527 P.2d 1075, 1076 (Ct. App. 1974), for the proposition that New Mexico has adopted the learned-intermediary doctrine. See Post-Hearing Memo. at 5 n.2. The Court, however, "must follow the decisions of intermediate state courts in the absence of convincing evidence that the highest court of the state would decide differently." Stoner v. New York Life Insurance Co., 311 U.S. at 467. The Court does not find the statements of courts outside of New Mexico and the Tenth Circuit about what the Court of Appeals of New Mexico did over twenty years ago -- although court statements -- persuasive evidence alone that the Supreme Court of New Mexico would adopt the learned-intermediary doctrine. As the Tenth Circuit explained in Wade v. Emcasco Insurance Co., "[u]ltimately . . . the Court's task is to predict what the state supreme court would do." 483 F.3d at 666. The Court concludes that there is convincing evidence, largely from the Supreme Court of New Mexico that the Supreme Court of New Mexico would not adopt the learned-intermediary doctrine, because the Court of Appeals of New Mexico cases that Eli Lilly relies on are old and much has changed in the landscape of drug manufacturing with the advent of direct-to-consumer advertising, and the relationship between doctors and patients. Thus, the Court finds convincing evidence in the Supreme Court of New Mexico's strict liability jurisprudence, the age of the Court of Appeals cases adopting the learned-intermediary doctrine, the modern realities of drug manufacturing, direct-to-consumer advertising, the importance of the internet in patients' medical decisionmaking, and the changing relationship between patients and doctors, that the Supreme Court of New Mexico would not adopt the learned-intermediary doctrine.

courts have held that the inadequacy of a drug company's warnings cannot be the proximate cause of the patient's injury when the physician failed to consult the literature or observe the warnings concerning the drug he used, . . . the better reasoned cases do not reach this result.” 95 N.M. at 681, 625 P.2d at 1198 (internal citations omitted). The Court of Appeals emphasized: “The issue, is still the foreseeability of the doctors’ actions. If it was foreseeable that doctors might not consult the PDR or package inserts before using [the medication], a doctor’s failure to do so does not constitute an independent intervening cause relieving a drug company, whose warnings were inadequate, from liability.” Id. at 680, 625 P.2d at 1198. The Court believes that the Supreme Court of New Mexico would find that the inadequacy of a drug company’s warnings can be a proximate cause of a patient’s injury -- not only when the doctor fails to consult the literature or the warnings -- but when the patient who does not.

Mark Rimbart contends that, if the Court finds that the Supreme Court of New Mexico would adopt the learned-intermediary doctrine, that the Court should find the Supreme Court would also adopt Section 6(d)(2) of the Restatement (Third) of Torts as an all-inclusive exception to the learned-intermediary doctrine. See Response at 12 n.11. Eli Lilly argues that Section 6(d)(2) of the Restatement (Third) of Torts was inapplicable to this case. See Reply at 12-16. Both Rimbart and Eli Lilly acknowledge that no New Mexico court has cited to this section of the Restatement (Third). See Response at 12 n.11; Reply at 12. Eli Lilly notes, however, that New Mexico state court opinions have cited to a version of the Restatement (Third) of Torts. See Post-Hearing Memo. at 10 n.5.⁶ Eli

⁶ Baldonado v. El Paso Natural Gas Company, 2008-NMSC-005, ¶ 14, 176 P.3d 277, 281 (citing Restatement (Third) of Torts § 32 cmt. d (Proposed Final Draft No. 1, 2005)); Payne v. Hall, 2006-NMSC-029, ¶ 14, 137 P.3d 599, 605 (citing Restatement (Third) of Torts: Apportionment of Liability § 26 (2000)); Berlangieri v. Running Elk Corp., 2003-NMSC-024, ¶ 18, 76 P.3d 1098, 1104 (citing Restatement (Third) of Torts: Apportionment of Liability § 2 (2000)); Herrera v. Quality Pontiac, 2003-NMSC-018, ¶ 20 n.2, 73 P.3d 181, 191 n.2 (citing Restatement (Third) of

Lilly contends that § 6 (d)(1) and (2) of the Restatement (Third) of Torts embody the learned-intermediary doctrine, and that, because New Mexico courts have cited favorably to the Restatement (Third) of Torts, although not specifically to those sections, the Court should predict that the Supreme Court of New Mexico would adopt the learned-intermediary doctrine. Eli Lilly contends that, “[g]iven the generally favorable citation to the Restatement (Third) of Torts and the number of New Mexico appellate cases recognizing and applying the substance of the learned intermediary doctrine as embodied therein, this Court should predict the New Mexico Supreme Court would continue to recognize the doctrine, either as articulated in appellate court precedent or in the Restatement (Third) of Torts.” Id. at 10 (underlining added). The Court continues to believe that the Supreme Court of New Mexico would not adopt the learned-intermediary doctrine, and notes that no New Mexico court has cited specifically to § 6(d)(1) or (2) supports that belief. The Court notes that the New Mexico courts have not always followed the Restatement (Second) of Torts.⁷

Torts: Liability for Physical Harm, § 6 cmt. f (Tentative Draft No. 2, 2002)); Lewis v. Samson, 1999-NMCA-145, ¶ 56, 992 P.2d 282, 295 (citing Restatement (Third) of Torts: Apportionment of Liability, § 50), rev’d, 2001 -NMSC- 035, 35 P.3d 972 (applying previous decisions and making no reference to the Restatement (Third) of Torts); Norwest Bank N.M., N.A. v. Chrysler Corp., 1999-NMCA-070, ¶ 11, 981 P.2d 1215, 1220 (citing Restatement (Third) of Torts § 50 Apportionment of Liability (Proposed Final Draft, 1998)); Spectron Dev. Lab. v. American Hollow Boring Co., 1997-NMCA-025, ¶¶ 13-27, 936 P.2d 852, 856-57 (1 of Restatement (Third) of Torts: Products Liability §§ 1, 2(a), 6(c) and cmt. d (Tentative Draft No. 2, 1995)); Baer v. Regents of University of California, 1999-NMCA-005, ¶ 12, 972 P.2d 9, 13 (citing of the Restatement (Third) of Torts §§ 50(b)(1) and (2) (Proposed Final Draft 1998) (Apportionment of Liability); Parker v. St. Vincent Hosp., 1996-NMCA-070, ¶ 4, 919 P.2d 1104, 1105 (Restatement (Third) of Torts: Products Liability § 1 (Tentative Draft No. 2, 1995)); Brooks v. Beech Aircraft Corp., 120 N.M. 372, 380, 902 P.2d 54, 62 (N.M. 1995)(citing Restatement (Third) of Torts: Products Liability § 2(b), at 9, 13 cmt. a (Tentative Draft No. 1, 1994)).

⁷ See Blake v. Pub. Serv. Co. of New Mexico, 2004-NMCA-002, ¶ , 82 P.3d 960 (rejecting the plaintiff’s argument that the Restatement (Second) of Torts § 324A was applicable in that case). Moreover, the Court notes that, in some product liability cases, the Supreme Court of New Mexico and the Court of Appeals of New Mexico do not cite to the Restatement (Second) of Torts and Restatement (Third) of Torts. See, e.g., Pharmaseal Laboratories, Inc. v. Goffe, 90 N.M. 753, 568

Because the Court does not believe that the Supreme Court of New Mexico would adopt the learned-intermediary doctrine, it is unnecessary for the Court to resolve whether the Supreme Court of New Mexico would adopt the exceptions to the learned-intermediary doctrine. The Court does not believe that the Supreme Court of New Mexico would create an exception to its strict-liability doctrine and then create exceptions to the exceptions. Specifically, because the Court has already determined that it does not believe that the Supreme Court of New Mexico would adopt the learned-intermediary doctrine, it is also unnecessary for the Court to determine whether, specifically, the Supreme Court of New Mexico would adopt the Restatement (Third) of Torts § 6(d)(2).

The Court notes, however, that the comment e to Restatement (Third) of Torts § 6 states:

. . . Subsection (d)(2) recognizes that direct warnings and instructions to patients are warranted for drugs that are dispensed or administered to patients without the personal intervention or evaluation of a health-care provider. . . . Although the learned intermediary rule is generally accepted and a drug manufacturer fulfills its legal obligation to warn by providing adequate warnings to the health-care provider, arguments have been advanced that in two other areas courts should consider imposing tort liability on drug manufacturers that fail to provide direct warnings to consumers. In the first, governmental regulatory agencies have mandated that patients be informed of risks attendant to the use of a drug. . . . Governmental regulations require that, when drugs are so advertised, they must be accompanied by appropriate information concerning risk so as to provide balanced advertising. The question in both instances is whether adequate warnings to the appropriate health-care provider should insulate the manufacturer from tort liability.

Restatement (Third) of Torts § 6 cmt. e. Comment e to the Restatement (Third) of Torts § 6 further explains: “The Institute leaves to developing case law whether exceptions to the learned intermediary rule in these or other situations should be recognized.” Id.

P.2d 589 (1977)(discussing a claim that was, in part, against the manufacturer of medical equipment); Martinez v. Showa Denko, K.K., 1998-NMCA-111, 964 P.2d 176 (discussing products liability action against manufacturer of L-Tryptophan (LT), a dietary supplement and the application of the discovery rule to products liability action where information known by consumer concerning the possible connection between her condition and her use of LT was sufficient to activate commencement of statute of limitations more than three years before filing of her complaint).

C. THE COURT WILL APPLY ITS RULING THAT THE SUPREME COURT OF NEW MEXICO WOULD NOT ADOPT THE LEARNED-INTERMEDIARY DOCTRINE TO THE PARTIES IN THIS CASE.

In Beavers v. Johnson Controls World Services, the Supreme Court of New Mexico set forth "retroactivity guidelines" for courts to consider in determining whether a decision should apply retroactively or prospectively:

First, the decision to be applied nonretroactively must establish a new principle of law, either by overruling clear past precedent on which litigants may have relied, or by deciding an issue of first impression whose resolution was not clearly foreshadowed.

Second, it has been stressed that we must . . . weigh the merits and demerits in each case by looking to the prior history of the rule in question, its purpose and effect, and whether retrospective operation will further or retard its operation.

Finally, we have weighed the inequity imposed by retroactive application, for where a decision of this Court could produce substantial inequitable results if applied retroactively, there is ample basis in our cases for avoiding the injustice or hardship by a holding of nonretroactivity.

Id. 118 N.M. at 398, 881 P.2d at 1384 (internal quotation marks and bracket omitted). Justice Scalia explained in Harper v. Virginia Department of Taxation, 509 U.S. 86 (1993), it "to be 'the province and duty of the judicial department to say what the law is,' -- not what the law shall be." 509 U.S. at 107 (Scalia, concurring)(emphasis in original)(quoting Marbury v. Madison, 5 U.S. 137, 177 (1803)). The Court believes that its conclusion that the Supreme Court of New Mexico would not adopt the learned-intermediary doctrine should apply to the parties in this case.

1. The Court's Prediction that the Supreme Court of New Mexico Would Reject the Learned-Intermediary Doctrine is Not a "New" Principle, and the Issue of Reliance is Less Important in the Tort Context.

The Court is predicting that the Supreme Court of New Mexico would reject the learned-intermediary doctrine, despite the Court of Appeals of New Mexico's decisions that adopt the learned-intermediary doctrine, in part because in the Supreme Court of New Mexico foreshadowed

its rejection in its strict liability jurisprudence. The rejection of the learned-intermediary doctrine is not thus "new," in the sense that the Supreme Court of New Mexico is reversing some of its long-standing precedent. Rather, to the Court, the Supreme Court of New Mexico's rejection of the learned-intermediary doctrine is "clearly foreshadowed by previous decisions" of the Supreme Court of New Mexico. Beavers v. Johnson Controls World Servs., 118 N.M. at 399, 881 P.2d at 1384 (emphasis in original).

Similar to the recognition of prima-facie tort in Schmitz v. Sementowski, that the Supreme Court of New Mexico discussed in Beavers v. Johnson Controls World Services, many jurisdictions have settled law on the learned-intermediary doctrine, including the Court of Appeals of New Mexico. As the Supreme Court of New Mexico explained in Beavers v. Johnson Controls World Services, however, "[i]n the tort context . . . a party's reliance interest is seldom as strong as it is in the commercial context. Stare decisis considerations are at their zenith in contract- and property-law settings; they lack that force in the area of tortious wrongs against others." 118 N.M. at 399, 881 P.2d at 1385. Eli Lilly relies on Montano v. Allstate Indemnity Co., 2004-NMSC-020, 92 P.3d 1255, for the proposition that it would work "considerable hardship and inequity" against it to reject the learned-intermediary doctrine. Specifically, Eli Lilly maintains that, unlike the defendant insurance company in Montano v. Allstate Indemnity Co., it was not on notice that "New Mexico courts would no longer recognize the learned intermediary doctrine."

In Montano v. Allstate Indemnity Co., the Supreme Court of New Mexico determined that "an insurance company should obtain written rejections of stacking in order to limit its liability based on an anti-stacking provision." 2004-NMSC-020, ¶ 19, 92 P.3d at 1260. The Supreme Court stated that it "recognize[d] that [its] holding . . . is a new, and not easily foreshadowed, aspect to [its] jurisprudence on stacking and that it would be inequitable to apply it against Allstate before it has had

an opportunity to alter its policy language; for those reasons, [the Supreme Court chose] to give it a purely prospective application." *Id.* ¶ 22, 92 P.3d at 1261.

The context of the dispute between Mark Rimbart and Eli Lilly is not contracts, unlike the dispute in Montano v. Allstate Indemnity Co., but is torts -- a context in which, as the Supreme Court has previously recognized in Beavers v. Johnson Controls World Services, reliance is less important. Thus, Eli Lilly's reliance on Montano v. Allstate Indemnity Co. is misplaced, because this is not a contract dispute. Moreover, Eli Lilly has not produced any evidence, or made any specific argument, showing how it relied on New Mexico's adoption of the learned-intermediary doctrine. Furthermore, the Court does not believe that the rejection of the learned-intermediary doctrine is unexpected, because of the Supreme Court of New Mexico's strict liability jurisprudence. Thus this factor favors retroactive application of the Court's holding that the learned-intermediary doctrine would be rejected by the Supreme Court of New Mexico.

2. Retroactive Application of the Court's Prediction that the Supreme Court of New Mexico Would Reject the Learned Intermediary Doctrine Will Further the Policies Discussed in the Supreme Court's Strict Liability Jurisprudence.

The Supreme Court of New Mexico explained in Brooks v. Beech Aircraft Corp. that the doctrine of strict liability is based on several policy concerns:

The policy of risk- or cost-distribution continues to serve as a primary basis for imposing strict products liability. . . . In addition to the cost-distribution rationale . . . other courts have approved specifically the rationale that imposing strict liability relieves plaintiffs of the burden of proving ordinary negligence under circumstances in which such negligence is likely to be present but difficult to prove. . . . The third policy cited for the imposition of strict liability is that suppliers who otherwise might not be liable because of a passive role in the chain of supply should be encouraged to select reputable and responsible manufacturers who generally design and construct safe products and who generally accept financial responsibility for injuries caused by their defective products. . . . Fourth and finally, imposing strict products liability serves the interests of fairness. . . . The fairness rationale embodies a normative judgment that plaintiffs injured by an unreasonably dangerous product should be compensated for

their injuries. At the heart of this judgment lies the conclusion that although the manufacturer has provided a valuable service by supplying the public with a product that it wants or needs, it is more fair that the cost of an unreasonable risk of harm lie with the product and its possibly innocent manufacturer than it is to visit the entire loss upon the often unsuspecting consumer who has relied upon the expertise of the manufacturer when selecting the injury-producing product.

120 N.M. at 375-76, 902 P.2d at 57-58 (internal citations omitted). As the Court previously explained, it believes that the Supreme Court of New Mexico would reject the learned-intermediary doctrine based on these policy concerns. Retroactive application of the Court's holding that the Supreme Court of New Mexico would reject the learned-intermediary doctrine would further the policies expressed by the Supreme Court's strict liability jurisprudence. Thus this factor favors retroactive application.

3. Although There is Some Hardship Imposed on Eli Lilly By Rejecting the Learned-Intermediary Doctrine, the Court Believes Rejection of the Doctrine Promotes Treating Similarly Situated Parties Alike.

Rejection of the learned-intermediary doctrine will impose some hardship on Eli Lilly, because other jurisdictions apply this doctrine. For the reasons stated previously, the Court believes that Eli Lilly's reliance, if any, is negligible in the torts context, because "it is doubtful that a tort victim ever relies on the availability of compensation before planning his or her activity," and "a potential tortfeasor may or may not rely on the likelihood vel non of liability in undertaking to act certain ways." Beavers v. Johnson Controls World Servs., 118 N.M. at 400, 881 P.2d at 1385. The Court is also taking into consideration "the potential unfairness to other claimants who have been victimized by conduct occurring before the law-changing decision but who for one reason or another have not asserted their claims until after announcement of the new rule." Id., 118 N.M. at 402, 881 P.2d at 1387 (emphasis in original). Drug manufacturers' relationship with patients has changed with the advent of direct-to-consumer advertising, and the rise of the internet as a medium of self-education for patients. These changes have also affected the relationship between doctors and patients. Thus,

the Court believes it would be unfair to other claimants to apply its holding, that the Supreme Court of New Mexico would reject the learned-intermediary doctrine, prospectively only.

As the Supreme Court noted in Beavers v. Johnson Controls World Services:

[U]neasiness or even dissatisfaction with a rule of law is not a reason for holding that the rule shall apply only prospectively. We must take the rule as we find it, articulated and justified in a thoroughly reasoned opinion of this state's highest court, and determine whether the rule should apply to conduct predating announcement of the rule, based on the analysis reviewed here and not on one's pleasure or displeasure over the rule itself.

118 N.M. at 401, 881 P.2d at 1386. Because the factors do not support application of its decision prospectively, the Court will apply its decision retroactively.⁸

II. THE COURT CANNOT STATE THAT THE WARNINGS WERE SUFFICIENT AS A MATTER OF LAW.

Eli Lilly contends that the Prozac warnings were adequate as a matter of law. See Memo. in

⁸ Mr. Vickery argued in his August 18, 2008 letter to the Court, that, even were the Court to "ignore the New Mexico presumption that its decision should apply retroactively, it would still presumably apply its decision in favor of the litigants in this case." August 18, 2008 Letter. "Pure prospectivity is rare." State ex rel. Martinez v. City of Las Vegas, 2004-NMSC-009, ¶ 50, 89 P.3d 47, 64 (internal quotation marks omitted). As the Supreme Court of New Mexico explained in Beavers v. Johnson Controls World Services, Inc.:

Pure prospectivity obtains when a court applies its new rule only to conduct occurring after the rule's announcement, so that the rule does not even apply to the litigants before the court announcing the decision. Pure prospectivity is rare; a notable example in New Mexico is Hicks v. State, 88 N.M. 588, 544 P.2d 1153 (1975), order and opinion on rehearing, 88 N.M. 593, 544 P.2d 1158 (1976) (abolishing sovereign immunity but only with respect to cases arising in future). Retroactivity, on the other hand, occurs when a decision applies not only to acts occurring after announcement of the decision and to the litigants before the court, but also to acts occurring before the announcement.

118 N.M. at 397 n.7, 881 P.2d at 1382. Thus, the Supreme Court of New Mexico's retroactivity analysis is still a necessary analysis for the Court to undertake, because pure prospectivity application is a rare, although potential possibility. In any case, while the Court need not decide whether its ruling applies to all possible tort victims, it should apply to these parties before the Court in this case.

Support at 20. Eli Lilly argues that the information in the precautions section of the Prozac Insert specifically addressed suicide. See id. Eli Lilly also asserts that the information provided in the adverse reactions section and post introduction report list suicide attempt, hostility, and akathisia. See id. at 21. Eli Lilly argues that such information “goes beyond that required to show adequacy of warning in the Serna v. Roche Labs case and establishes the adequacy of Lilly’s warning in the present case.” Id.

Under New Mexico law, the adequacy of warnings are usually a question of fact. See, e.g., Wilchinsky v. Medina, 108 N.M. at 516, 775 P.2d at 718 (“The timing and adequacy of any warnings, if given, are fact questions for the jury to decide in order to determine the proportionate fault, if any, of the physician.”); Michael v. Warner/Chilcott, 91 N.M. at 655, 579 P.2d at 187 (“In reversing the case, we held that adequacy of the warning given by a manufacturer in a negligence action presents an issue of fact for the jury. In making this determination, we said: ‘The warning must adequately indicate the scope of the danger.’”)(quoting First Nat. Bank, Albuquerque v. Nor-Am Agr. Prod., Inc., 88 N.M. at 83, 537 P.2d at 692). As the Court of Appeals stated in Perfetti v. McGhan Med.:

Defendant's claim is based on the surgeon's general knowledge of the danger of deflation and that deflation could occur at any time. This mistakes the danger involved and, thus, the warning that was required. Defendant's duty was to warn of the nature and extent of the danger of a leak developing because of wear of the prosthesis at a fold resulting from capsular contracture. There was a factual question for the jury as to the surgeon's knowledge of this danger; the trial court could not have properly ruled on the surgeon's knowledge as a matter of law.

99 N.M. at 651, 662 P.2d at 650.

In Serna v. Roche Labs, the plaintiff alleged that no warnings were given about the possible dangers of the medication. See 101 N.M. at 524, 684 P.2d at 1189. The Court of Appeals stated that the adequacy of a warning to a physician is determined by the following criteria:

1. the warning must adequately indicate the scope of the danger; 2. the warning must

reasonably communicate the extent or seriousness of the harm that could result from misuse of the drug; 3. the physical aspects of the warning must be adequate to alert a reasonably prudent person to the danger; 4. a simple directive warning may be inadequate when it fails to indicate the consequences that might result from failure to follow it and, most importantly, in the context of the present case; 5. the means to convey the warning must be adequate.

Id., 684 P.2d at 1189. The Court of Appeals found that the package insert for the medication and the PDR listing of “Stevens-Johnson Syndrome” in the section on allergic reactions was a prima-facie showing of adequacy. Id. at 525, 684 P.2d at 1190. The plaintiff in Serna v. Roche Labs did not introduce “evidence which would support a factual question as to the adequacy of the warnings.” Id. at 525, 684 P.2d at 1190. If the nonmovant presents evidence of the inadequacy of the warnings, however, “it is improper for the court to grant summary judgment for the drug manufacturer. Here, plaintiff presented no evidence of the inadequacy of the warnings and summary judgment [wa]s proper.” Id., 684 P.2d at 1190.

At the time that Dr. Hochstadt prescribed Prozac for Gilbert Rimbart, the Prozac package insert and the PDR contained the following statement in the “Precautions” section:

Suicide -- The possibility of a suicide attempt is inherent in depression and may persist until significant remission occurs. Close supervision of high risk patients should accompany initial drug therapy. Prescriptions for Prozac should be written for the smallest quantity of capsules consistent with good patient management, in order to reduce the risk of overdose.

Prozac Insert at 2; PDR at 5 (emphasis in original). The reference to suicide in the “Precautions” section of the labeling in 2003 was in regard to suicide as a consequence of depression. Response at 3. The “Adverse Reactions” sections of the Prozac Insert and the PDR also reference suicide attempt, akathisia, and hostility. Prozac Insert at 4; PDR at 7. The “Postintroduction Reports” section of the Prozac Insert and the PDR also listed suicidal ideation and violent behaviors as being included in post-marketing reports of adverse events temporally associated with Prozac. Prozac Insert at 4; PDR at 7.

A black-box warning identifying a possible risk of increased suicidality in pediatric patients and young adults treated with SSRIs was added to the Prozac labeling and Prozac Insert sometime in 2004. See Hochstadt Depo. at 16:9-15, id. at 20:11-15. The federal regulations required and require a warning in the “Warnings” section about the risk of Prozac-induced suicidality. Response, Exhibit 3, 2003 Prozac label at 9; 21 C.F.R. §§ 201.57(e)(June 30, 2006) and 314.70(c)(2)(i). Mark Rimbart asserts that the “passing references to akathisia or suicidality or hostility or violence in other sections of the labeling that are not ‘warnings’ are irrelevant.” Response at 3.

In the fall of 2004, the FDA decided that, in addition to the black-box warning on the label or the package insert for physicians, patients need to be warned directly via “Patient Medication Guides” about the risks at issue in this lawsuit. Response at 5; Patient Medication Guide. Dr. Hochstadt testified that, now that the black box warnings regarding suicide have been implemented, he warns patients about the risk of antidepressant-associated suicidality. See id. at 49:15-25. Mark Rimbart’s disclosed expert, Dr. Jackson, has opined:

Had Lilly provided an adequate warning about the risks of Prozac to Gilbert Rimbart, his family and his physicians; had Lilly provided an adequate warning about the necessity of vigilant monitoring (particularly when changing dose, or initiating and terminating drug therapy); and had Lilly promptly communicated the facts about the likelihood of treatment-emergent suicidality and the early worsening of depression, it is quite possible that the violent deaths of Gilbert Rimbart, his wife, and his dog could have been avoided.

Jackson Report at 52.⁹

⁹ Eli Lilly has filed a Daubert motion to preclude Dr. Jackson from opining in this case and a separate motion for summary judgment for Mark Rimbart’s alleged lack of expert testimony to support his claims. See Defendant Eli Lilly and Company’s Motion to Exclude Expert Testimony of Dr. Grace Jackson, filed March 20, 2008 (Doc. 58); Defendant Eli Lilly and Company’s Motion for Summary Judgment Based on Lack of Admissible Expert Testimony on General, Specific and Proximate Causation, filed March 20, 2008 (Doc. 67). The Court need not, and will not, decide the admissibility of Dr. Jackson’s testimony on this motion, but will address that issue on Eli Lilly’s Daubert motion. For purposes of this motion, the Court will assume Dr. Jackson’s testimony is

Unlike the plaintiff in Serna v. Roche Labs, Mark Rimbart has presented some evidence that the Prozac warnings may have been inadequate. See 101 N.M. at 525, 684 P.2d at 1190 (“Here, plaintiff presented no evidence of the inadequacy of the warnings and summary judgment [wa]s proper.”). Moreover, under New Mexico law, the adequacy of warnings are usually a question of fact. See Wilchinsky v. Medina, 108 N.M. at 516, 775 P.2d at 718; Michael v. Warner/Chilcott, 91 N.M. at 655, 579 P.2d at 187; Perfetti v. McGhan Med., 99 N.M. at 651, 662 P.2d at 650. The Court cannot say that, as a matter of law, the Prozac warnings in 2003 were adequate. There is an issue of material fact regarding whether the warnings were adequate, and thus Eli Lilly is not entitled to summary judgment on Mark Rimbart’s failure-to-warn claim as a matter of law.

III. THERE IS A GENUINE ISSUE OF MATERIAL FACT REGARDING THE CAUSE OF GILBERT AND OLIVIA RIMBERT’S DEATHS.

“[W]here the moving party has the burden -- the plaintiff on a claim for relief or the defendant on an affirmative defense -- his showing must be sufficient for the court to hold that no reasonable trier of fact could find other than for the moving party.” Paul v. Monts, 906 F.2d at 1474 (internal quotations omitted). Under New Mexico law, “[i]f, in light of all the circumstances of this case, [an adequate warning] [adequate directions for use] would have been noticed and acted upon to guard against the danger, a failure to give [an adequate warning] [adequate directions for use] is a cause of

admissible. Accordingly, Eli Lilly's arguments regarding causation in its Post-Hearing Memorandum will be addressed by the Court on Eli Lilly’s Daubert motion. See Post-Hearing Memo. at 14 (stating that a warning is only required when "there is 'reasonable evidence of an association of a serious hazard with a drug,'" and stating "the FDA has specifically rejected -- and continues to reject -- any association between adult use of Prozac . . . and suicide or violence." (quoting 21 C.F.R. § 201.57(e)(2006) and citing Colacicco v. Apotex, Inc., 521 F.3d 253, 271 (3d Cir. 2008)("Thus, even when it began to reevaluate its position regarding the association of antidepressants with pediatric and adolescent suicidality, the FDA continued to announce its rejection of adult suicidality warnings for SSRIs as it had for the decade before the prescriptions and deaths at issue in this litigation."))).

injury.” N.M.R.A., Civ. UJI 13-1425. N.M.R.A., Civ. UJI 13-1424 states that:

The cause of an injury is that which, in a natural and continuous sequence [unbroken by any independent intervening cause], contributes to bringing about the injury and without which the injury would not have occurred. [It need not be the only cause, nor the last nor nearest cause. It is sufficient if it occurs with some other cause, acting at the same time, which, in combination with it, causes the injury.]

["Independent intervening cause" is that which interrupts the natural sequence of events which could reasonably be expected to result from the condition in which a product was sold or from a foreseeable manner of use. An independent intervening cause unforeseeably turns aside the course of events and produces a result which could not reasonably have been expected.]

Id. (emphasis added).

Eli Lilly contends that, because Dr. Hochstadt testified that he would have prescribed Gilbert Rimbart Prozac, even knowing there had been concerns raised regarding suicide and violence, Mark Rimbart cannot prove, as a matter of law that Eli Lilly’s alleged failure to warn caused Gilbert and Olivia Rimbart’s deaths. See Memo. in Support at 26-27. Dr. Hochstadt also testified, however, that now that the black-box warnings regarding suicide have been implemented, he warns patients about the risk of antidepressant-associated suicidality. See Hochstadt Depo. at 49:15-25. There is thus a material issue of fact regarding whether Eli Lilly’s alleged failure to properly warn Gilbert Rimbart and Dr. Hochstadt proximately caused Gilbert and Olivia Rimbart’s deaths.

Under New Mexico law, “[t]he voluntary, willful act of suicide is a new or intervening agency that breaks the chain of causation.” Johnstone v. City of Albuquerque, 2006-NMCA-1191, ¶ 22, 145 P.3d at 83. Consequently, where the record reveals such a deliberate, intentional act of suicide, summary judgment is appropriate because proximate causation cannot be proven. See id., ¶ 28, 45 P.3d at 85. The Court of Appeals noted: “Courts generally decline to impute a duty to the defendant when he neither caused the decedent's uncontrollable suicidal impulse nor had custody of the decedent and knowledge of her suicidal ideation.” Id. ¶ 10, 45 P.3d at 81 (internal quotation marks omitted).

In Richards v. Upjohn Co., however, the Court of Appeals reversed summary judgment granted for the defendant drug company in a suit arising out of personal injuries suffered by the plaintiff which allegedly resulted from medical treatment by a medication manufactured by the defendant. See 95 N.M. at 676, 625 P.2d at 1193. The Court of Appeals noted that “[p]roximate cause is a factual issue, unless all facts regarding causation are undisputed or, as a matter of law, there is an independent intervening cause.” Id. at 678, 625 P.2d at 1195. The Court of Appeals stated that “[i]t is improper for a court on summary judgment proceedings to decide that the warnings of a manufacturer of a drug that is dangerous if misused are adequate as a matter of law if evidence of inadequacy is presented.” Id. at 679, 625 P.2d at 1196. The Court of Appeals also held that “[a] doctor’s negligence is not, as a matter of law, an intervening cause exonerating the drug company, if the doctor’s act is reasonably foreseeable.” Id., 625 P.2d at 1196. The Court of Appeals summarized: “The issue, is still the foreseeability of the doctors’ actions. If it was foreseeable that doctors might not consult the PDR or package inserts before using [the medication], a doctor’s failure to do so does not constitute an independent intervening cause relieving a drug company, whose warnings were inadequate, from liability.” Id. at 680, 625 P.2d at 1198.

The Court believes that Eli Lilly has not carried its burden to prove that Gilbert Rimbart’s suicide was an intervening cause. Dr. Jackson testified that, to bring about the death of his dog, his wife, and ultimately himself, Gilbert Rimbart had to engage in eleven deliberative acts. See Jackson Depo. at 129:17-135:1. In her report, Dr. Jackson opined:

Had Lilly provided an adequate warning about the risks of Prozac to Gilbert Rimbart, his family and his physicians; had Lilly provided an adequate warning about the necessity of vigilant monitoring (particularly when changing dose, or initiating and terminating drug therapy); and had Lilly promptly communicated the facts about the likelihood of treatment-emergent suicidality and the early worsening of depression, it is quite possible that the violent deaths of Gilbert Rimbart, his wife, and his dog could have been avoided.

Jackson Report at 52.

Dr. Jackson could not eliminate alternative causes of the deaths of Gilbert and Olivia Rimbart. See id. at 148:22-149:3; id. at 149:12-22. “Contributory negligence and independent intervening cause are questions for the jury, unless, as a matter of law, there is no evidence upon which to submit the issue to the jury.” City of Belen v. Harrell, 93 N.M. at 604, 603 P.2d at 714. While Eli Lilly contends that Gilbert Rimbart’s acts were purposeful and intentional and thus Mark Rimbart cannot “prove proximate cause because Gilbert’s voluntary, deliberate, and intentional act in carrying out the suicide constitutes an independent intervening cause that breaks the causal sequence of the event and thus absolves Lilly of liability for its alleged failure to warn,” Memo. in Support at 32, under New Mexico law, the cause of an injury “need not be the only cause, nor the last nor nearest cause. It is sufficient if it occurs with some other cause, acting at the same time, which, in combination with it, causes the injury.” N.M.R.A., Civ. UJI 13-1424.

In Johnstone v. City of Albuquerque, the Court of Appeals of New Mexico rejected the claim that the decedent’s stepfather was responsible for her suicide because the decedent used his gun and he was a police officer. See 2006-NMCA-119, ¶¶ 1-2, 145 P.3d at 78. The Court of Appeals stated:

When an individual commits suicide using a gun owned by someone else, the owner of the gun is not liable for the death under settled negligence principles. In the absence of intentional conduct that creates the risk of suicide, or a legally recognized special relationship and knowledge of a specific likelihood of harm that gives rise to a duty to avoid harm, suicide operates as an independent intervening cause of death. In this case, we decline Plaintiff’s invitation to abrogate this long-standing precedent. Defendant’s sixteen year-old stepdaughter used his firearm to commit suicide. Her estate sued him individually, together with his employer the City of Albuquerque, alleging that Defendant was grossly negligent in leaving his firearm unattended. Summary judgment was entered for Defendant in his individual capacity, dismissing Plaintiff’s suit. We affirm.

Id. ¶ 1, 145 P.3d at 78 (emphasis added). There are two exceptions to this general rule. See id. ¶ 11, 145 P.3d at 81. One is when the actor’s tortious conduct induces a mental illness in the decedent from

which the death results. See id., 145 P.3d at 81. This exception is described in the Restatement (Second) of Torts § 455:

If the actor's negligent conduct so brings about the delirium or insanity of another as to make the actor liable for it, the actor is also liable for harm done by the other to himself while delirious or insane, if his delirium or insanity

(a) prevents him from realizing the nature of his act and the certainty or risk of harm involved therein, or

(b) makes it impossible for him to resist an impulse caused by his insanity which deprives him of his capacity to govern his conduct in accordance with reason.

Restatement (Second) of Torts § 455.

The other exception applies when there is “a duty that results from a special relationship between the decedent and the defendant, that presumes or includes knowledge of the decedent’s risk of suicide.” Id., 145 P.3d at 81. “Special relationships typically involve treatment relationships, such as mental health professionals and their patients, and persons having direct custody and control over the decedent.” Id. ¶ 14, 142 P.3d at 81. Other special relationships are set forth in the Restatement (Second) of Torts, §§ 314A and 315-319. Restatement (Second) of Torts § 314A sets forth special relationships giving rise to a duty to aid or protect:

(1) A common carrier is under a duty to its passengers to take reasonable action

(a) to protect them against unreasonable risk of physical harm, and

(b) to give them first aid after it knows or has reason to know that they are ill or injured, and to care for them until they can be cared for by others.

(2) An innkeeper is under a similar duty to his guests.

(3) A possessor of land who holds it open to the public is under a similar duty to members of the public who enter in response to his invitation.

(4) One who is required by law to take or who voluntarily takes the custody of another

under circumstances such as to deprive the other of his normal opportunities for protection is under a similar duty to the other.

Restatement (Second) of Torts § 314A. The Restatement (Second) of Torts explains that there is no duty to control the conduct of a third party to prevent him or her from causing physical harm to another unless a special relationship exists between the actor and the third party imposing a duty on the actor to control the third party's conduct, or a special relationship between the actor and another which gives the third party a right to protection. See Restatement (Second) of Torts § 315. These special relationships include the relationship between a parent and child, see Restatement (Second) of Torts § 316, an employer and employee, see id. at § 317, an actor who allows another to use his or her land or chattels, see id. at § 318, or someone who takes charge of a person "whom he knows or should know to be likely to cause bodily harm to others if not controlled is under a duty to exercise reasonable care to control the third person to prevent him from doing such harm," id. at § 319.

There are conflicts of material fact whether Gilbert Rimbert's actions were foreseeable, and thus, whether Eli Lilly owed a duty to Gilbert Rimbert. While, generally, suicide is an independent intervening cause that absolves a defendant of liability, there are two exceptions to this general rule: (i) when the defendant's tortious conduct induces a mental illness in the decedent from which the death results and (ii) when there is a duty that results from a special relationship between the decedent and the defendant, that presumes or includes knowledge of the decedent's risk of suicide.

Unlike the defendant in Johnstone v. City of Albuquerque, it is not clear, as a matter of law, that there is an "absence of intentional conduct [by Eli Lilly] that creates the risk of suicide" in the deaths of Gilbert and Olivia Rimbert. 2006-NMCA-119, ¶ 1, 145 P.3d at 78. The Court of Appeals explained in Johnstone v. City of Albuquerque that "[f]oreseeability of injury is not the sole consideration in establishing a duty, since a person's duty to another is also tempered by policy

considerations.” Id. ¶ 9, 145 P.3d at 80. The Court of Appeals stated:

In determining the existence of a duty, we look at the relationship of the parties, the nature of the plaintiff's interest and the defendant's conduct, and the public policy in imposing a duty on the defendant. . . . We look at both foreseeability and whether the obligation of the defendant is one to which the law will give recognition and effect. . . . The assessment of foreseeability takes into account community moral norms and policy views, tempered and enriched by experience, and subject to the requirements of maintaining a reliable, predictable, and consistent body of law.

Id., 145 P.3d at 80.

In 2008, there is a black-box warning that contains the words of caution for patients of “all ages.” Response, Exhibit 2, Prozac Insert at 1, available at: www.prozac.com (“2008 Prozac Insert”). As of August of 2003, however, when Dr. Hochstadt prescribed Prozac for Gilbert Rimbart, there was no black-box warning. See Complaint ¶¶ 2, 32-36, 48(c), 51, 55, at 1, 11-12, 15, 16; Plewes Aff. at 1-2, Prozac Insert at 6.

Mark Rimbart contends that the risk of akathisia, mania, psychosis, violence, activation, and/or suicide is dose dependent. See Response ¶ 44, at 3-4; Beasley article at 40-46; Defendant Eli Lilly and Company’s Answer to Plaintiff’s Complaint ¶ 13 at 5, filed November 20, 2006 (“Lilly admits that some, but not all, adverse events associated with the use of Prozac appear to be dose related.”). Mark Rimbart asserts that, “[i]n other words, if one is already sensitive to Prozac-induced side effects, for whatever reason, increased dosing exacerbates the issue.” Response at ¶ 44, at 4. Mark Rimbart maintains that the FDA agrees. See Response ¶ 44, at 4; Prozac Insert at 10 (stating that “[a]ll patients being treated with antidepressants for any indication should be monitored appropriately and observed closely for clinical worsening, suicidality, and unusual changes in behavior, especially during the initial few months of a course of drug therapy, or at times of dose changes, either increases or decreases.”).

Family members found an unfilled prescription for Prozac written for Gilbert Rimbart when

they cleaned the home after his death. See id. at 15:15-17:4. Toxicological examination confirmed the presence of fluoxetine and its psychoactive metabolite, norfluoxetine, in Gilbert Rimbart's blood. See Response, Exhibit 5, National Medical Services, Inc. Toxicology Report at 1. The homicide/suicide in this case occurred sixteen days after Gilbert's dose of Prozac was doubled. Memo. in Support at ¶¶ 32, 39, at 10-11.

Accordingly, the Court believes there is a genuine issue of material fact whether Eli Lilly's allegedly tortious conduct in failing to warn Gilbert Rimbart about possible Prozac-induced murder and suicide induced a mental illness in Gilbert Rimbart resulting in death. There is a genuine issue of material fact whether Gilbert Rimbart's ingestion of Prozac induced a mental illness in Gilbert from which deaths resulted. The Court believes that there is a genuine issue of material fact regarding the cause of the deaths of Gilbert and Olivia Rimbart.

Dr. Jackson testified that Gilbert Rimbart engaged in deliberate acts. She also testified, however, that it was possible that a prompt warning about the likelihood of alleged suicidality resulting from Prozac treatment could have prevented the deaths of Gilbert Rimbart, his wife, and his dog.¹⁰ Because there is a genuine issue of material fact regarding the cause of Gilbert Rimbart's death, and because there is a genuine issue of material fact regarding whether Gilbert Rimbart's suicide was an intervening cause absolving Eli Lilly of liability, Eli Lilly is not entitled to summary judgment as a matter of law.

Under New Mexico law, Eli Lilly may also be tortuously liable for Gilbert and Olivia Rimbart's deaths if it owed a duty to Gilbert Rimbart because it had a special relationship with him. These special relationships are described in §§ 314A, 315-319 of the Restatement (Second) of Torts.

¹⁰ Again, the Court will decide the admissibility of this testimony on Eli Lilly's Daubert motion, not on this motion, and here will assume Dr. Jackson's testimony is admissible.

The Court does not believe that there is a genuine issue of material fact whether Eli Lilly owed Gilbert Rimbart a duty because of a special relationship. Eli Lilly is not a special carrier, Gilbert Rimbart's employer, and Gilbert Rimbart was not in Eli Lilly's custody. Thus, the special relationships described in the Restatement (Second) of Torts do not apply to the relationship, if any, between Gilbert Rimbart and Eli Lilly. Moreover, the Court does not believe that Mark Rimbart attempts to establish that Eli Lilly owed Gilbert Rimbart a duty because of a special relationship.

IV. THE COURT WILL NOT GRANT ELI LILLY SUMMARY JUDGMENT ON MARK RIMBART'S STRICT LIABILITY CLAIMS AS A MATTER OF LAW.

New Mexico had adopted the basis for products liability found in Restatement (Second) of Torts § 402A (1965). See Serna v. Roche Labs, 101 N.M. at 523, 684 P.2d at 1188. The Restatement (Second) of Torts § 402A provides:

(1) One who sells any product in a defective condition unreasonably dangerous to the user or consumer or to his property is subject to liability for physical harm thereby caused to the ultimate user or consumer, or to his property, if

(a) the seller is engaged in the business of selling such a product, and

(b) it is expected to and does reach the user or consumer without substantial change in the condition in which it is sold.

(2) The rule stated in Subsection (1) applies although

(a) the seller has exercised all possible care in the preparation and sale of his product, and

(b) the user or consumer has not bought the product from or entered into any contractual relation with the seller.

Restatement (Second) of Torts § 402A. To succeed on a cause of action brought under a theory of strict products liability, a plaintiff must prove five elements: (i) the product was defective; (ii) the product was defective when it left the hands of the defendant and was substantially unchanged when it reached the use or consumer; (iii) that because of the defect the product was unreasonably dangerous

to the use or consumer; (iv) the consumer was injured or was damaged; (v) the defective condition of the product was the proximate cause of the injury or damage. See Armeanu v. Bridgestone/Firestone North Am. Tires, L.L.C., 2006 WL 4060666 at *3. In the context of pharmaceutical cases, New Mexico courts have adopted comment k to § 402A of the Restatement (Second) of Torts. See Hines v. St. Joseph's Hosp., 86 N.M. at 764, 527 P.2d at 1076.

New Mexico courts have recognized that the doctrine of products liability is applicable to three defects: design, manufacturing, and marketing (warnings). See Morales v. E.D. Etnyre and Co., 382 F.Supp. 2d at 1264 (citing Smith v. Bryco Arms, 2001-NMCA-090, ¶ 8, 33 P.3d at 643 and Fernandez v. Ford Motor Co., 118 N.M. at 109, 879 P.2d at 110). “New Mexico's ‘unreasonable-risk-of-injury’ test allows for proof and argument under any rational theory of defect.” Smith ex rel. Smith v. Bryco Arms, 2001-NMCA-090, ¶ 14, 33 P.3d at 644 (quoting Brooks v. Beech Aircraft Corp., 120 N.M. at 379, 902 P.2d at 61).

Eli Lilly argues that Mark Rimbert's strict-liability claim fails as a matter of law, because he cannot prove a manufacturing defect. See Memo. in Support at 32-34. Eli Lilly contends that Dr. Jackson offered no opinion regarding any alleged defect in the manufacture of the Prozac allegedly ingested by Gilbert Rimbert. See id. at 34. Mark Rimbert concedes that he is “not pursuing either a design or manufacturing defect claim.” Response at 21. Mark Rimbert contends, however, that he is pursuing a “marketing defect claim.” Id. Mark Rimbert contends that “evidence concerning Lilly's failure to warn or instruct establishes a prima facie, triable case of a marketing defect.” Id.

Eli Lilly also argues that Prozac is an “unavoidably unsafe product” within the meaning of comment k to the Restatement (Second) of Torts. Memo. in Support at 34. Eli Lilly contends that “there is no alternative design for the chemical compound known as fluoxetine hydrochloride which is the only active component or ingredient” in Prozac, and that Prozac “is a scientific constant and

Lilly could not manufacture it with any other composition and still manufacture ‘Prozac.’” Id. Eli Lilly also contends that Mark Rimbert’s failure-to-warn claim under strict liability should fail for the same reasons as that claim under negligence. See id. at 35-36.

Mark Rimbert argues that Lilly “chose to avoid warnings of Prozac-induced violence and suicidality until 2005, when the FDA made [it] start warning. Because Lilly has proffered no proof whatsoever that it provided legally adequate warnings about this risk to anyone prior to August of 2003, it is not entitled to summary judgment on this affirmative defense.” Response at 22.

In Hines v. St. Joseph’s Hospital, the Court of Appeals of New Mexico found that no process could destroy the virus, which the plaintiff received from the tainted blood, without damaging the blood, and thus, the blood was a product incapable of being made safe for its intended and ordinary use. See 86 N.M. at 764, 527 P.2d at 1076. In Hines v. St. Joseph’s Hospital, the Court of Appeals specifically found that summary judgment was appropriate for the blood-provider defendant, because: “Blood Services placed a warning on the blood container and also ‘constantly distributed’ an ‘Official Circular of Instructions for Use’ to the hospital staff. Dr. Hurley, who gave the transfusion, stated he knew of the danger of hepatitis transmission in blood transfusions. Blood Services’ warning was adequate.” 86 N.M. at 764, 527 P.2d at 1076.

Unlike the tainted blood in Hines v. St. Joseph’s Hospital, Eli Lilly has not demonstrated that there is no process to make Prozac safely without destroying Prozac. While arguing that fact, Eli Lilly has made no effort to demonstrate that to be the case in its motions. Moreover, Eli Lilly also has not demonstrated that Prozac could not be made safe through alternative warnings.

Although Eli Lilly has argued that there is no way to alternatively design Prozac, it maintains that the analysis for Mark Rimbert’s strict-liability claim is the same as Mark Rimbert’s failure-to-warn claim under negligence. See Memo. in Support at 35. The Court has already determined that it

cannot say, as a matter of law, the Prozac warnings were adequate in 2003. There is an issue of material fact regarding whether the warnings were adequate, and thus Eli Lilly is not entitled to summary judgment on Mark Rimbart's failure-to-warn claim as a matter of law.

Moreover, the Court notes that, under New Mexico law, "[w]hether a product is unreasonably dangerous, and therefore defective, is ordinarily a question for the jury." Smith ex rel. Smith v. Bryco Arms, 2001-NMCA-090, ¶ 14, 33 P.3d at 644. "The jury instructions covering strict products liability are designed to encourage a risk-benefit calculation by defining 'unreasonable risk of injury' in a way which requires the jury to balance meritorious choices for safety made by the manufacturer while minimizing the risk that the public will be deprived needlessly of beneficial products." Id., 33 P.3d at 644. There are genuine issues of material fact regarding the cost-benefit decisions Eli Lilly made in deciding what warnings to distribute with Prozac in 2003 and the risk that the public would be deprived of Prozac's benefits.

The Court believes that there are genuine issues of material fact whether Eli Lilly's Prozac warnings were adequate, and whether Prozac is an unavoidably unsafe product within the meaning of comment k to the Restatement (Second) of Torts. Because there are genuine issues of material fact, Eli Lilly is not entitled to summary judgment on Mark Rimbart's strict-liability claim as a matter of law.

V. THE COURT WILL GRANT ELI LILLY SUMMARY JUDGMENT ON MARK RIMBERT'S CLAIM FOR NEGLIGENCE PER SE.

Eli Lilly contends that Mark Rimbart "identifies no state law, regulation or industry standard that Lilly allegedly violated. Rather, [Mark Rimbart] premises his negligence per se claim only on Lilly's alleged violation of a federal regulation related to prescription drugs." Memo. in Support at 36 (citing 21 C.F.R. § 201.57(e)). Mark Rimbart counters that the Federal Food Drug and Cosmetic

Act and its regulations and statutes do not change the common law duty to warn, but “merely set minimal standards.” Michael v. Warner/Chilcott, 91 N.M. at 654, 579 P.2d at 186 (“The Defendant still owes a duty to warn of dangers of which it knew or should have known in the exercise of reasonable care.”)(internal quotation marks omitted). Specifically, Mark Rimbart states:

Interestingly, although Lilly mentions its preemption defense in passing in this Memorandum, with regard to the per se negligence claim as a result of its violation of the FDA regulation, Lilly ignores the recent teachings of the Supreme Court, i.e. that a federal law “does not prevent a State from providing a damages remedy for claims premised on a violation of the FDA regulations; the state duties in such a case ‘parallel,’ rather than add to, federal requirements.” Riegel v. Medtronic, Inc., 128 S.Ct. 999, 1011 (2008).

Response at 22.

The Court will assume, for the purpose of Eli Lilly’s Motion to Summary Judgment on All Claims, that this claim is not preempted by federal law. The Court has entered an order staying briefing on Eli Lilly’s motion for summary judgment on preemption pending the Supreme Court of the United States’ ruling in Levine v. Wyeth, 944 A.2d 179 (Vt. 2006), cert. granted, --- U.S. ---, 128 S.Ct. 1118 (2008), see Memorandum Opinion and Order, filed April 23, 2008 (Doc. 80). The Court will decide the preemption issue on that motion and not in connection with this motion.

Mark Rimbart is bringing this claim under state law. Under New Mexico law, to establish a negligence per se claim, Mark Rimbart must prove: (i) that there is a statute which prescribes certain actions or defines a standard of conduct, either explicitly or implicitly; (ii) that the defendant violated the statute; (iii) that the plaintiff must be in the class of persons sought to be protected by the statute; and (iv) that the harm or injury to the plaintiff must generally be of the type the legislature through the statute sought to prevent. See Johnstone v. City of Albuquerque, 2006-NMCA-119, ¶ 16, 145 P.3d at 82. To hold a defendant liable under a claim of negligence per se, the defendant must be shown to have violated a specific statute or regulation. See Parker v. E. I. DuPont de Nemours and Co., Inc.,

121 N.M. at 132, 909 P.2d at 12. Under New Mexico law, violation of a regulation may be the basis for liability on a negligence per se claim. See N.M.R.A, Civ. UJI 13-1501 (stating that “[i]f the court finds that a regulation may be the basis for a claim of negligence per se, this instruction may be modified accordingly.”); Abeita v. N. Rio Arriba Elec. Co-op, 1997-NMCA-097, ¶ , 946 P.2d 1108 (finding no reversible error in a court giving the jury N.M.R.A, Civ. UJI 13-1501 and the defendant did not “suggest on appeal that the regulations should be treated differently from statutes for the purpose of instructing the jury on negligence per se.”); Hinger v. Parker and Parsley Petroleum Co., 120 N.M. 430, 440, 902 P.2d 1033, 1043 (Ct. App. 1995)(holding that there was sufficient evidence to support a verdict against the defendant for negligence per se based on the violation of various statutes and regulations regarding operation of gas wells).

The Court of Appeals of New Mexico has implied that a plaintiff could have a claim for negligence per se based on federal law. See Parker v. DuPont de Nemours and Co., Inc., 121 N.M. at 131, 909 P.2d at 12 (holding that summary judgment was appropriately granted for the defendant when the plaintiffs alleged a claim for negligence per se based on the defendant’s alleged violations of federal law and the plaintiffs failed to show that the defendant “violated any state or federal statute.”)(emphasis added). 21 C.F.R § 201.57(e)(1996) provides guidance regarding: “Warnings. Under this section heading, the labeling shall describe serious adverse reactions and potential safety hazards, limitations in use imposed by them, and steps that should be taken if they occur.” Id.

Eli Lilly contends that private litigants cannot enforce the Federal Food, Drug and Cosmetic Act through private actions. See Cottrell Ltd. v. Brotrol Int’l Inc., 191 F.3d 1248, 1255 (10th Cir. 1999)(stating that “claims that require direct interpretation and application of the FDCA are not properly recognized because such matters are more appropriately addressed by the FDA, especially in light of Congress’s intention to repose in that body the task of enforcing the FDCA.”)(quoting

Braintree Labs, Inc. v. Nephro-Tech, Inc., No. 96-2459-JWL, 1997 WL 94237 at *6 (D.Kan. February 26, 1997)). In Cottrell Ltd. v. Brotrol International Inc., the Tenth Circuit was interpreting the Environmental Protection Agency ("EPA") clearance of the claims made on pesticide, cleaner, and disinfectant labels, and Federal Insecticide, Fungicide, and Rodenticide ("FIFRA") law. See 191 F.3d at 1248. The parties in Cottrell Ltd. v. Brotrol International Inc. manufactured, advertised, and marketed hard-surface cleaners and disinfectants. See id. at 1250. The Tenth Circuit stated that it found "instructive an unpublished memorandum and order from the United States District Court for the District of Kansas which involved similar issues in a case involving the federal Food, Drug, and Cosmetics Act ('FDCA')." Id. at 1254 (citing Braintree Labs, Inc. v. Nephro-Tech, Inc., 1997 WL 94237).

In Braintree Labs, Inc. v. Nephro-Tech, Inc., the court granted the defendant's motion to dismiss the plaintiff's claim for violation of the Lanham Act. See 1997 WL 94237 at *2. The district court explained: "Although the Tenth Circuit has not considered the effect of section 337(a), every federal court that has addressed the question has held that the FDCA does not create a private right of action to enforce or restrain violations of its provisions." Id. at * 3 (citing Bailey v. Johnson, 48 F.3d 965, 967 (6th Cir. 1995); PDK Labs, Inc. v. Friedlander, 103 F.3d 1105 (2d Cir.1997); Gile v. Optical Radiation Corp., 22 F.3d 540 (3d Cir. 1994); Mylan Labs., Inc. v. Matkari, 7 F.3d 1130 (4th Cir. 1993); Pacific Trading Co. v. Wilson & Co., 547 F.2d 367 (7th Cir.1976)). In Braintree Labs, Inc. v. Nephro-Tech, Inc., the court believed it was

significant that Congress, before passing the FDCA, considered and rejected a version which would have allowed a private right of action for damages. . . . If a private right of action were recognized, the major advantages of enforcement through the FDA would be lost, including expertise, ability to solicit comment from appropriate sources, direct representation of the public interest, and a unitary enforcement policy. . . . The court concludes that the Tenth Circuit would agree with the analysis of its sibling circuits and hold that violations of the FDCA may not be alleged by private right of

action.

Braintree Labs, Inc. v. Nephro-Tech, Inc., No. 96-2459-JWL, 1997 WL 94237 at *3 (internal citations, quotation marks, and bracket omitted). The court further explained

claims that require direct interpretation and application of the FDCA are not properly recognized because such matters are more appropriately addressed by the FDA, especially in light of Congress's intention to repose in that body the task of enforcing the FDCA. The court believes that the Tenth Circuit would embrace these general principles.

Id. at *6. The Tenth Circuit found the district court's framework in Braintree Labs, Inc. v. Nephro-Tech, Inc. "serve[d it] well." Cottrell Ltd. v. Brotrol Int'l Inc., 191 F.3d at 1255.

Unlike the federal claims in Cottrell Limited v. Botrol International Inc. (EPA and FIFRA) and Braintree Labs, Inc. v. Nephro-Tech, Inc. (Lanham Act) this case involves a state claim. While the Court assumes, for the purposes of this motion, that federal law does not preempt state law,¹¹ the Court believes that Mark Rimbert's claim for negligence per se is foreclosed by the Tenth Circuit's favorable citation to and quotations from Braintree. Although Cottrell Ltd. v. Brotrol Int'l Inc. did not directly address the FDCA, the Tenth Circuit indicated that the court's analysis in Braintree Labs, Inc. v. Nephro-Tech, Inc. -- that the FDCA does not create a private right of action to enforce or restrain violations of its provisions -- was instructive and reflected the Tenth Circuit's framework.

On a clean slate, the Court might not be inclined to follow the district court's analysis in Braintree Labs, Inc. v. Nephro-Tech, Inc. Under New Mexico law, the FDCA and its regulations do not change the common-law duty to warn, but "merely set minimal standards." Michael v. Warner/Chilcott, 91 N.M. at 654, 579 P.2d at 186 ("The Defendant still owes a duty to warn of dangers of which it knew or should have known in the exercise of reasonable care.")(internal quotation

¹¹ The Court will decide the preemption issue directly when it rules on Eli Lilly's preemption motion. See Doc. 19.

marks omitted). However, the Tenth Circuit has indicated that the FDCA does not create a private right of action to enforce or restrain violations of its provisions. While the Court might be prepared to draw a distinction between private rights of action and claims for negligence per se, the Tenth Circuit's quotation from Braintree that "claims that require direct interpretation and application of the FDCA are not properly recognized" seems, fairly read, to prohibit negligence per se claims based on the FDCA and its regulations. See also Talley v. Danek Medical, Inc., 7 F.Supp.2d at 731 (holding that "the FDCA expressly prohibits the bringing of a private cause of action under the Act. . . . To allow a state negligence per se action based upon alleged violations of the FDCA would defeat the purpose of that prohibition. Accordingly, the Court finds that [the defendant] is entitled to summary judgment on [the plaintiff]'s FDCA-based negligence per se claim."); In re: Orthopedic Bone Screw Products Liability Litigation, 193 F.3d at 791 (holding that "[p]laintiffs' [negligence per se] theory would undermine section 337(a) by establishing a private state-law cause of action for violations of the FDCA, so long as those actions are brought against more than one defendant."); Compare In re: Orthopedic Bone Screw Products Liability Litigation, 193 F.3d at 790 (stating that some state law "make[s] clear the doctrine of per se liability does not create an independent basis of tort liability but rather establishes, by reference to a statutory scheme, the standard of care appropriate to the underlying tort.") with Heath v. La Mariana Apartments, 2008-NMSC-017, ¶ 23 n.3, 180 P.3d 664, 670 ("We also clarify that negligence per se should not be equated with strict liability. . . . A defendant can rebut an allegation of negligence per se with proof of an excuse for the violation, a possibility that is not allowed for in strict liability.").¹²

¹² To the extent that the § 337(a) issue is a preemption issue, the Court will decide the preemption issues on Eli Lilly's preemption motion. The issue here is more narrow: Is New Mexico's claim for negligence per se a private cause of action under the FDCA, or merely another way to prove negligence. The Court merely decides that negligence per se with reference to the

Eli Lilly notes, in support of its motion for summary judgment on the basis of preemption, filed March 9, 2008 (Doc. 20), that the FDA has “explained how state tort law claims could interfere with and frustrate FDA’s public health mission and regulation of prescription drug labeling.” *Id.* at 29. While Eli Lilly does not expressly argue that 28 U.S.C. § 337 would prevent state-law tort claims based on violations of FDA regulations, the Court believes that Eli Lilly is raising a similar argument in its motion for summary judgment on the basis of preemption, by contending that state tort claims could interfere with the FDA’s mandates.

The Court need not decide whether a claim for negligence per se based on violation of federal regulations under New Mexico law is preempted by federal law. The Court also need not determine whether negligence per se is a separate tort under New Mexico law, or whether it is only a doctrine through which a plaintiff may demonstrate the defendant’s liability for violation of a duty of care embodied in a statute. It appears that, while New Mexico law contemplates violation of federal statutes or regulations as a possible basis for a negligence per se claim, the Tenth Circuit has indicated that “claims that require direct interpretation and application of the FDCA” are foreclosed. The Court is not certain how it could let proceed a negligence per se claim based on the FDCA and its regulations without interpreting and applying in some way the FDA’s regulations. Because the Tenth Circuit has indicated that such a private cause of action for violation of the FDCA is foreclosed, Eli Lilly is entitled to summary judgment as a matter of law on Mark Rimbert’s negligence per se claim.

VI. THE COURT WILL GRANT ELI LILLY SUMMARY JUDGMENT ON MARK RIMBERT’S WARRANTY CLAIMS, BECAUSE HE CONCEDES THAT SUMMARY JUDGMENT ON THOSE CLAIMS IS APPROPRIATE.

Mark Rimbert concedes that, in light of Perfetti v. McGhan Medical, 99 N.M. at 650, 662 P.2d

FDCA is another way of proving negligence under state law and does not establish a private cause of action under the FDCA.

at 649, summary judgment on his warranty claims is appropriate. See Response at 23. Mark Rimbart has not demonstrated that there was any bargaining between Eli Lilly and Gilbert Rimbart and has not demonstrated that Eli Lilly made any affirmations that were part of any bargain between Eli Lilly and Gilbert Rimbart. See Perfetti v. McGhan Medical, 99 N.M. at 652, 662 P.2d at 653 (“The surgeon's testimony is to the effect that, not only was there no ‘dickered’ aspects, the affirmations were not part of any bargain between defendant and the surgeon.”). Thus, the Court will grant Eli Lilly summary judgment on Mark Rimbart’s warranty claims.

VII. ELI LILLY IS NOT ENTITLED TO SUMMARY JUDGMENT ON MARK RIMBERT’S PUNITIVE DAMAGES CLAIM, BECAUSE HE HAS PRODUCED SUFFICIENT EVIDENCE TO DEMONSTRATE THAT THERE IS A GENUINE ISSUE OF MATERIAL FACT WHETHER ELI LILLY ACTED WITH RECKLESS DISREGARD, WILFULNESS, WANTONNESS, MALICIOUSNESS, OPPRESSIVENESS, OR FRAUD.

Mark Rimbart contends that there is “voluminous evidence of Lilly’s conscious indifference.” Response at 23. Mark Rimbart contends that internal Eli Lilly documents establish that it was aware of the problem of Prozac-induced violence for many years. See id. Mark Rimbart also contends that the “bulk of the internal documents that establish Lilly’s consciousness of this problem, at the highest twelfth floor levels of the corporate hierarchy, stem from the wake of this publication” of a peer-reviewed journal article by Harvard neuropsychopharmacologists which found six patients developed suicidality after initiation of Prozac therapy. Response at 24 (citing M. Teicher, C. Glod, and J. Cole, Emergence of Intense Suicidal Preoccupation During Fluoxetine Treatment, 147:2 Am. J. Psychiatry. 207-10 (1990)).

Eli Lilly contends that Mark Rimbart “cannot survive summary judgment on his request for punitive damages because there is no evidence of willful or wanton conduct by Lilly.” Memo. in Support at 42. Eli Lilly argues that Mark Rimbart has not produced any admissible evidence to

support his allegations that its actions demonstrated willful misconduct, malice, fraud, wantonness, oppression, or entire want of care. See id.

To be liable for punitive damages, a wrongdoer must have some culpable mental state and the wrongdoer's conduct must rise to a willful, wanton, malicious, reckless, oppressive, or fraudulent level. See Clay v. Ferrellgas, Inc., 118 N.M. at 269, 881 P.2d at 14. "Recklessness in the context of punitive damages is the intentional doing of an act with utter indifference to the consequences." Couch v. Astec Indus., Inc., 2002-NMCA-084, ¶ 58, 53 P.3d 398, 411 (internal quotation marks omitted).

In a product liability case, the knowledge factor is extremely important. A defendant that is unaware of a product's defect can hardly 'consciously' or 'recklessly' disregard any other party's rights. Numerous cases bear out the proposition that with every award of punitive damages, the defendant-manufacturer was aware of the existing defect and also aware of the serious danger of substantial harm posed by that defect.

Faniola v. Mazda Motor Corp., 2004 WL 1354469 at *6 (internal quotation marks and bracket omitted).

The Court believes that Mark Rimbart has adduced some proof that Eli Lilly may have been aware of the alleged defect in Prozac. Moreover, "[w]hether conduct arises to the level such that punitive damages are appropriate is a mixed issue of fact and law." N.M. Banquest Investors Corp. v. Peters Corp., 2007-NMCA-065, ¶ 29, 159 P.3d at 1127.

On February 7, 1990, an internal e-mail was circulated. See Response, Exhibit 16, e-mail from Leigh Thompson to Allan J. Weinstein, Patrick P. Keohane, Max W. Talbott, and Robert L. Zerbe (dated February 7, 1990)("February 7, 1990 e-mail"). The e-mail stated, in part:

. . . the resource needs to stay absolutely on top of every Prozac adverse event report. Anything that happens in the UK can threaten this drug in the US and worldwide. We are now expending enormous efforts fending off attacks because of (1) the relationship to murder and (2) inducing suicidal ideation. The appropriate level of response is indicated by Dan Masica himself and Charles Beasley immediately flying to Boston to talk to authors of paper on suicidal ideation. . . . The FDA is very skitterish . . . We must not allow ONE DAY to elapse on followup, flying to, investigating, etc.

everything about Prozac. . . . There cannot be a fumble of even minor proportions on this one, because political pressure and perception and public news, NOT SCIENCE, could cause us to lose this one !!!!!

Id. A second e-mail was circulated on February 7, 1990. See Response, Exhibit 17, e-mail from Leigh Thompson to Allan J. Weinstein (dated February 7, 1990)(“Second February 7, 1990 e-mail”).

That e-mail stated, in relevant part:

I am concerned about reports I got re UK attitude towards Prozac safety. Leber suggested a few minutes ago we are using the CSM database to compare Prozac aggression and suicidal ideation with other antidepressants in the UK. Although he is a fan of Prozac and believes a lot of this is garbage, he is clearly a political creature and will respond to the pressures. I hope Patrick realizes that Lilly can go down the tubes if we lose Prozac and just one event in the UK can cost us that.

Id. On January 24, 1990, an e-mail was sent from Charles Beasley, Jr. to Leigh Thompson, Allan J. Weinstein, and Robert L. Zerbe. See Response, Exhibit 18 (“January 24, 1990 e-mail”). This e-mail stated:

RE: PROZAC AND SELF-DIRECTED VIOLENCE

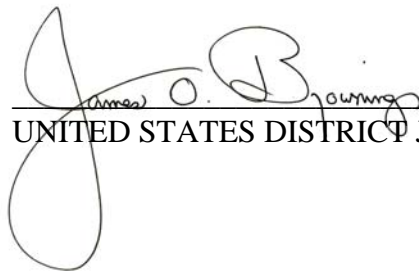
We have just received a pre-print of an article (not a letter to ed.) which we understand is to appear in the February 1990, AMERICAN JOURNAL OF PSYCHIATRY suggesting that Prozac can induce severe, intense, obsessional suicidal ideation. The evidence is six complex cases (weak evidence in our opinion) Copies are being distributed. We have previously instituted an analysis of our US Clinical Trials Database for byoindication, by time-of-exposure rates of other-directed violence, self-directed violence, and mental states which might be considered by some to predispose patients to the actions. The Montgomery parasuicide study may also provide scientific data relative to this issue. It is important to keep in mind that some of the more prominent researchers in this area (violence) consider self-directed and other-directed acts to be very similar in their biological substrates.

Id.

Mark Rimbart has demonstrated that persons at Eli Lilly may have been aware of a problem, perceived or actual, linking Prozac with increased suicidality and violence. Thus, the Court believes that there are genuine issues of material fact whether Eli Lilly acted with reckless disregard for the

rights of Mark Rimbert, or with willfulness, wantonness, maliciousness, oppressiveness, or fraudulently. A factfinder may infer from Eli Lilly's internal documents that it was aware of an alleged problem with Prozac, suicidality, and violence in 1990 before the 2003 Prozac warnings were issued and before events in 2003 underlying this lawsuit occurred. Because there is a genuine issue of material fact whether Eli Lilly acted with the requisite intent, Eli Lilly is not entitled to summary judgment on Mark Rimbert's claims for punitive damages.

IT IS ORDERED that Defendant Eli Lilly and Company's Motion to Summary Judgment on All Claims is granted in part and denied in part. Eli Lilly and Company is entitled to summary judgment on Plaintiff Mark Gilbert Rimbert's warranty and negligence per se claims. The Court will deny Eli Summary Judgment on all of Mark Rimbert's remaining claims for negligence, strict liability, and punitive damages.



UNITED STATES DISTRICT JUDGE

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